S. 1009, THE CHEMICAL SAFETY IMPROVEMENT ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

FIRST SESSION

NOVEMBER 13, 2013

Serial No. 113–92

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PRINTING OFFICE

87–628 PDF WASHINGTON : 2014

For sale by the Superintendent of Documents, U.S. Government Printing Office
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C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

[1] Mr. Vitter and Mr. Udall did not submit written statements for the record.

[2] Mr. Igrejas did not answer submitted questions for the record by the time of printing.

S. 1009, THE CHEMICAL SAFETY IMPROVEMENT ACT

WEDNESDAY, NOVEMBER 13, 2013

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:18 a.m., in room 2123 of the Rayburn House Office Building, Hon. John Shimkus (chairman of the subcommittee) presiding.

Members present: Representatives Shimkus, Gingrey, Pitts, Murphy, Latta, Cassidy, McKinley, Bilirakis, Johnson, Tonko, Pallone, Green, DeGette, Capps, McNerney, Dingell, Barrow, and Waxman (ex officio).

Staff present: Nick Abraham, Legislative Clerk; Charlotte Baker, Press Secretary; Jerry Couri, Senior Environmental Policy Advisor; Brad Grantz, Policy Coordinator, Oversight and Investigations; David McCarthy, Chief Counsel, Environment and the Economy; Brandon Mooney, Professional Staff Member; Andrew Powaleny, Deputy Press Secretary; Chris Sarley, Policy Coordinator, Environment and the Economy; Jacqueline Cohen, Democratic Senior Counsel; Greg Dotson, Democratic Staff Director, Energy and Environment; and Caitlin Haberman, Democratic Policy Analyst.

Mr. SHIMKUS. I would like to call the hearing to order.

We want to welcome our two Senators. First, I will do—we will do our opening statements, and then we will give you yours and then—and we will begin. I recognize myself for 5 minutes.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Today we hold our fourth hearing of 2013 on the Toxic Substance Control Act. We welcome our witnesses, including a couple of former House guys; Senator Vitter and Senator Udall, as well as Jim Jones, Assistant Administrator of the EPA, and some of the important stakeholders in this discussion.

Until more recently, TSCA was one of the least understood Federal environmental laws, but it is one of the most important environmental protections laws that we have. It governs chemical substances, mixtures and articles from the time they are invented, all the way through the stream of commerce.

Our hearings have been very instructive. They have given us a chance to dig into the nuts and bolts of this complex body of law. Among other aspects of the law, we studied approval of new chemicals, regulation of existing chemicals, protection of confidential

business information, and the value of a seamless integrated U.S. market for chemicals and products that contain them. We have gotten the perspective of learned experts in the practice of TSCA law, former EP officials experienced in what works and what doesn't work in the law's administration, State environmental control officials, downstream product manufacturers, and citizen activists.

As we will hear firsthand in just a few minutes, a lot of thought and hard work has also gone into TSCA on the other side of the Capitol. Earlier this year, Senator Vitter and the late Senator Frank Lautenberg, with strong bipartisan support, introduced Senate Bill 1009, the Chemical Safety Improvement Act. Its reform, if enacted, will represent the most sweeping set of changes to TSCA since the Ford administration.

We are eager to learn what aspects of this proposal brought such a diverse set of supporters together. We hope this administration and our panel will tell us what they see as the best attributes of the legislation. We also hope to entertain suggestions on how to make it better.

Writing legislation as complex and as important as modernizing TSCA is not easy, but implementing it may be even tougher. Congress can give EPA both the authority and direction to carry out everything in a new TSCA, but we just can't assume that the Agency has the resources to accomplish all of it, nor that they will get it done in a short period of time of enactment. That is why we need some guidance from Jim Jones, who manages the chemical regulation for the EPA. Mr. Jones, we hope your help won't end with today's hearing. The same goes for stakeholders, and not only the ones we will hear from today. We need your help in understanding the real world implications of any legislation we might consider. No one, whether on this side of the dais or on the witness table, has all the answers, but that doesn't mean we don't need you to give us all of your input.

And, finally, thanks to all the members of the subcommittee for your thoughtful work this year on TSCA. Have you noticed that our hearings have not been debates across the aisle, but rather nonpartisan efforts to understand the current law? At times, I have learned as much from questions from Mr. Tonko or Ms. DeGette, and the answers witnesses give them, as I have from my own brilliant questions that I have offered.

Let us continue to embrace that same spirit as we begin to explore whether we can make Federal chemical management policy better, and allow the United States to lead the global—the globe in manufacturing smarter public health protection and innovation.

[The prepared statement of Mr. Shimkus follows:]

PREPARED STATEMENT OF HON. JOHN SHIMKUS

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Until more recently, TSCA was one of the least understood Federal environmental laws, but it is one of our most important environmental protection laws. It governs chemical substances, mixtures, and articles from the time they are invented all the way through the stream of commerce. Our hearings have been very instructive.

They've given us a chance to dig into the nuts and bolts of this complex body of law.

Among the aspects of the law, we've studied:

- Approval of new chemicals,
- Regulation of existing chemicals,
- Protection of confidential business information, and
- The value of seamless, integrated U.S. market for chemicals and products that contain them.

We've gotten the perspective of:

- Experts in the practice of TSCA law;
- Former EPA officials experienced in what works and what doesn't work in the law's administration;
- State environmental control officials;
- Downstream product manufacturers; and
- Citizen activists.

As we'll hear first-hand in just a few minutes, a lot of thought and hard work has also gone into TSCA on the other side of the Capitol. Earlier this year Senator Vitter and late-Senator Frank Lautenberg with strong bipartisan support introduced S. 1009, the Chemical Safety Improvement Act. Its reforms, if enacted, would represent the most sweeping set of changes to TSCA since the Ford administration.

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Let's continue to embrace that same spirit as we begin to explore whether we can make Federal chemical management policy better and allow the United States to lead the globe in manufacturing, smarter public health protection, and innovation.

Mr. SHIMKUS. With that, I yield back the balance of my time, and I yield 5 minutes to Mr. Tonko, the ranking member of the subcommittee.

OPENING STATEMENT OF HON. PAUL TONKO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TONKO. Thank you, Mr. Chair, and good morning. I am pleased to be here today for this important hearing on the Chemical Safety Improvement Act. It is a pleasure to welcome Senator Vitter and Senator Udall here to discuss their perspectives on TSCA, TSCA reform, and report on their ongoing efforts to reconcile the interests of the many constituencies who have a deep stake in chemical issues. It is not an easy task.

This is our subcommittee's fourth hearing on TSCA. There seems to be general agreement by all parties that the current law simply is not working. Current law does not give the Environmental Protection Agency the tools or the resources the agency needs to implement an effective toxic chemical program, but general agreement

on these observations is no guarantee of agreement on the best way to address these problems. And it appears we still have some disagreement about which aspects of TSCA are in need of revision.

The public does not have confidence in this law or EPA's implementation of it. Industry's assertion that its products are safe is simply not good enough. Because the Federal law is ineffective, States have stepped in to address specific chemical risks. State action provides an essential backstop to Federal law, but individual State actions do not provide a uniform safety guarantee to all of our citizens, and they do not provide national standards and regulatory certainty to industry.

So where do we go from here?

The bipartisan initiative represented by S. 1009 offers us an opportunity for broad participation in the effort to reform TSCA, and that is what we need; broad participation in this effort. Because chemicals are such a part of our daily lives, we all have a stake in this effort. This bill does not yet address many of the current law's shortcomings. In some respects, it takes us backward by preempting States' ability to act, for example.

There is no need for a State preemption. If this proposal provides EPA with the tools to protect all of our citizens, including those who are the most vulnerable; children and our elderly, there will be far less call for individual State action, but States should retain their rights to act in the best interests of their citizens, and to address specific State concerns when, indeed, it is necessary.

I am concerned about retaining the unreasonable risk standard from current law when it has not proven to be a sufficient basis for Agency action over the past 37 years.

EPA cannot evaluate the potential risk or relative safety of chemicals without sufficient information. The fact is we still have many chemicals circulating in commerce for which we have little health and safety information, and even less about their behavior in the environment. This problem stems from several weaknesses in the current law, which this legislation only partially addresses. We need a Federal chemical law that provides adequate protection of public health and the environment, and that promotes continued innovation in our chemical industry.

The Chemical Safety Improvement Act does not yet achieve the right balance between these important goals, but with additional work it could. We have a very knowledgeable and experienced group of individuals here today who will offer constructive suggestions to this subcommittee about how to proceed.

Thank you for being with us this morning. I look forward to hearing your views on the Chemical Safety Improvement Act, and your recommendations for creating what needs to be an effective chemical safety law.

Thank you, and I yield back.

Mr. SHIMKUS. Gentleman yields back his time. The Chair now seeks anyone need time on the majority side. Seeing none, the Chair now recognizes the chairman emeritus, Mr. Dingell, for 5 minutes.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. I thank you for holding this hearing. This is a valuable act, and I am much appreciative to you.

We need to know what is going on with regard to TSCA, the Toxic Substances Control Act. It is long past time to reform this law. EPA has not been able to tackle even the most dangerous of chemicals and substances, and we may need to find a way to fix this problem.

There has been only a few successes of TSCA since it was signed into law by my good friend from Michigan, former member of this body, our good friend, President Gerald Ford. During the House floor debate on TSCA, I was successful in proposing an amendment to phase out the use of PCBs. That, I think, and six other substances are about all that TSCA has been able to remove from the trade.

We are finding out today what kind of negative effects PCBs have on the food chain, human health, wildlife and water quality. Frankly, it is very bad, and they remain a part of the chain even though they have been long removed. My amendment was supported by industry and by the environmentalists, and was adopted by a voice vote. Those kinds of things are possible to do, and I would note that we think that industry and the others who are concerned with these matters can work together, and I hope that this committee will give them the chance so to do.

The most recent change to TSCA happened only a few years ago when I was chairman of the committee, and when we passed the Mercury Export Ban Act. I have here a letter from 2007 penned by the National Mining Association and Natural Resources Defense Council, the American Chemistry Council, the Environmental Council of State, and McLaren Institute in support of that legislation, and I ask unanimous consent that it be inserted in the record.

Mr. SHIMKUS. Without objection, so ordered.

[The information follows:]

October 23, 2007

The Honorable John Dingell
2328 Rayburn House Office Building
U.S. House of Representatives
Washington, DC 20510

Re: HR 1534

Dear Chairman Dingell:

HR 1534, the "Mercury Export Ban Act of 2007", which bans the export of surplus mercury into global commerce, was reported out of Subcommittee on August 2, 2007. At that time, a bipartisan commitment was made to seek resolution of the outstanding concerns regarding the bill before consideration by the full Committee.

The undersigned organizations have since participated in the ensuing discussions and negotiated in good faith to produce an amendment to HR 1534 to be offered at full Committee (amendment dated October 22, 2007 (4:36pm)) which addresses our individual concerns, advances our shared objective of reducing global mercury pollution, and reflects good public policy.

Specifically, the negotiated version of HR 1534 establishes a practical and workable domestic framework for sequestering the elemental mercury prohibited from export under the legislation. To develop this framework, our organizations worked diligently and collectively to reach consensus, each of us agreeing not to raise related mercury matters which may have prevented a successful outcome. Therefore we hope the Committee will acknowledge the compromises made and pass our consensus language without further changes.

In closing, the undersigned organizations support the negotiated version of HR 1534 and urge its passage.

Sincerely,

Frances G. Beinecke, President
Natural Resources Defense Council

R. Steve Brown, Executive Director
Environmental Council of States

Jack N. Gerard, President & CEO
American Chemistry Council

Arthur E. Dungan, President
The Chlorine Institute, Inc.

Kraig R. Naasz, President & CEO
National Mining Association

cc: Members of the Energy and Commerce Committee

Mr. DINGELL. And I thank you for that.

The reason I suggest this is it shows that we can work together where there is the will, and your leadership, I hope, will provide us that necessary requirement.

My point here is that any overhaul of TSCA must include broad support from industry, environmental and conserver groups. From the time that we passed the Clean Air Act amendments of 1977, this committee has held frequent hearings over the next 13 years until we ultimately passed the Clean Air Act amendments of 1990. An interesting story about that was, somebody said, Dingell, what a great thing you did in getting this bill through the House in 13 hours. I said, yes, it only took me 13 years to do it. But the harsh fact of the matter is these things take a lot of hard work, and a lot of time and a lot of cooperation.

I think industry and others who have concerns on this, consumers and environmentalists, are willing to work together, and your leadership, I think, will be of enormous value in achieving that great goal.

There has been much debate on the—in the Senate about the legislation before us, and I am pleased to see that we have two of our former colleagues from the Senate over here to discuss these matters with us. Before supporting any legislation, however, I would hope that the broad support that we saw from the Mercury Export Ban in 2007, and for TSCA in 1976, will be available.

I do look forward to today's hearings, and I commend you, and I hope that we can find compromises that will gain not just the 218 votes on the House floor, but will come closer to the unanimity that we have seen on other legislation that has come out of this committee, including the Clean Air Act, which we passed by an overwhelming majority with, I think, less than 10 votes against it. So I hope that we can work together. The task will be difficult. The problem is very complex, and I think the challenge is great, but I am hopeful that the members of the committee can pull together on this, your leadership will be successful, and that we will accomplish the great goal of cleaning up the mess that we have on TSCA, and seeing to it that it works with the other problems that we have in connection with Clean Air, Superfund and all the other difficulties that we confront.

I thank you for your courtesy to me, Mr. Chairman.

Mr. SHIMKUS. Gentleman yields back his time. Now the Chair would like—again, wants to welcome our former colleagues from the House, now U.S. Senators, back to the House side and to the Energy and Commerce Committee room. This has been an issue that has been going on for many years, and Senator Vitter and I sat down 3 years ago, and—when he started working with Senator Lautenberg on this. So we are glad to have you present, and I would recognize each of you 5 minutes. That is not a hard time. And then we will dismiss you and we won't put you up to questions from your former colleagues. Who knows what they would ask.

So with that, we would like to recognize Senator David Vitter from Louisiana for 5 minutes.

STATEMENTS OF HON. DAVID VITTER, A UNITED STATES SENATOR FROM THE STATE OF LOUISIANA; AND HON. TOM UDALL, A UNITED STATES SENATOR FROM THE STATE OF COLORADO

STATEMENT OF HON. DAVID VITTER

Mr. VITTER. Thank you very much, Chairman Shimkus and Ranking Member Tonko and all the members for this invitation. Senator Udall and I are really excited to be here to talk about our work, particularly over the last few months, to ensure that S. 1009, the Chemical Safety Improvement Act, which I had the real honor and pleasure of introducing with Frank Lautenberg, continues to improve, and ultimately gets us to where we need to be so that finally, after 37 long years, we modernize and repair the badly-outdated Toxic Substances Control Act.

Today's hearing is a huge step in the right direction, and I know it is continuing your work, the fourth hearing that you have had on this important topic, and I am really excited to see your work and see it dovetail with our work.

The Lautenberg-Vitter Bill, which is currently co-sponsored by a very bipartisan and politically-diverse quarter of the U.S. Senate, was the product of extensive negotiations, and I believe it exemplifies solid positive bipartisan compromise and good policy. But while we were putting together the bill initially, certainly, Frank Lautenberg and I never thought we had perfect legislation. And so that is why I have been honored to partner with Senator Udall since Frank's passing, to strengthen S. 1009, and we have committed ourselves to meeting with anyone interested in achieving significant bipartisan TSCA reform.

After a long hearing, for instance, in July in our Senate committee, and countless hours of meetings, we fully recognize the issues that have been raised, some legitimate, some not, with the Lautenberg-Vitter Bill. And I think it has made—been made abundantly clear, but I will certainly say it again, and I know Senator Udall agrees, anyone interested in achieving meaningful bipartisan compromise to ensure TSCA reform protects all Americans in all 50 States, not just a small segment of the population, or the financial interests of some particular constituency, anyone who has those interests has a welcome seat at the table. And I am confident that by working with Senator Udall and interested stakeholders, the EPA, all of you, other members, co-sponsors of S. 1009 and others, will achieve a final version that not only enhances business certainty and creates a strong Federal chemicals management system, but also sets meaningful deadlines and protects the most vulnerable among us, effectively screens all active chemicals in commerce, and guarantees Americans access to private rights of action and legal remedies, and makes certain that EPA has the tools necessary to ensure the chemicals that we are all exposed to are indeed safe.

Now, as I said, anyone interested in a meaningful, substantive result and bipartisan compromise is welcome to a seat at the table, but I do want to urge that the Lautenberg-Vitter Bill, which was the product of a lot of hard work and real compromise itself, is the core and the foundation that we build from. Frank himself called

that compromise an historic step that would "fix the flaws with current law." Vice President Biden referred to our efforts as a "bipartisan breakthrough." In a statement from Senator Lautenberg's widow, Bonnie, she remembered, "Frank told me that this bill would be bigger and could save more lives than his law to ban smoking on airplanes." And in her words, "passage of this bill would be a wonderful cap to his career and testament to his legacy."

So S. 1009 is Senator Lautenberg's legacy bill, and I hope we work hard to improve it, take up any significant legitimate issue. We have been doing that through my work with Senator Udall, but in doing that, I hope we do not go back, quite frankly, to failed previous efforts that were completely stuck-in-the-mud on partisan lines. And so, again, I want to urge us to stick to this core as we improve it and pass it into law.

I would be remiss not to mention the work that went into achieving this compromise with Frank, because it didn't happen overnight, didn't happen without a lot of work and a lot of give-and-take from both of us. He was a very talented legislator committed to making the world a better place. I enjoyed arguing and negotiating and working with him. Frank's wife, Bonnie, was there to take pictures the day Frank and I shook hands on the core pivotal agreement, and again, I am really pleased and honored that Senator Udall and I have partnered carrying on that work and that legacy to get it across the finish line.

Again, I want to thank each and every one of you for all of your work on TSCA, I know it has been ongoing, and specifically for this hearing as part of that continuing conversation.

Thank you for the invitation.

Mr. SHIMKUS. Thank you. And the Chair now recognizes Senator Udall. And, sir, you are recognized for 5 minutes.

STATEMENT HON. TOM UDALL

Mr. UDALL. OK. Thank you very much for the invitation to be here today, and I really in particular want to thank Chairman Shimkus and also Ranking Member Tonko.

We—Senator Vitter and I both appreciate this opportunity. And let me just, at the beginning, just say what a pleasure it has been working with Senator Vinner—Vitter and all of the stakeholders to try to center-in on something that we think can get through the Senate, and also I hope will be received over here with some kudos and applause.

S. 1009, the Chemical Safety Improvement Act, has been the center of a lot of debate and discussion in the Senate since its introduction. When I first cosponsored the legislation, I did so for two reasons; one, I believed the bill addressed some of the key flaws in TSCA, and that has been noted here. There have been a number of flaws there. And I was very moved by the spirit of bipartisan compromise led by Senator Frank Lautenberg and Senator Vitter in an area where the two parties are often very far apart.

My staff and I and Senator Vitter's staff have spent many months since the introduction, working on this legislation and working with the various stakeholders. S. 1009 is not perfect, and, as introduced, has some key problems that need to be addressed.

As Senator Lautenberg's successor, as chairman of the Senate Subcommittee on Superfund, Toxics and Environmental Health, I respect the criticism the bill is receiving, and I strongly believe several key areas must be addressed for this legislation to be successful.

Chairwoman Boxer held a hearing on this issue earlier this year which delved into these issues. I applaud this committee for taking similar action.

I think many of these problems are unintentional, but many in the environment and health community believe these issues mean this legislation should not move forward as-is, and given the fact that we are talking about one of the most ineffective laws on the books, that is worth noting. I agree that we should not pass S. 1009 as introduced, but I am, and will continue to be, optimistic about the incredible bipartisan spirit around finding reform and protecting our families from dangerous chemicals.

As the subcommittee chair, I want to develop and pass legislation that safeguards our citizens. S. 1009 has a number of strong elements of needed reform, as well as problems. We can, building off of that, and that is why I have committed so much time to working with Senators of both parties to improve this bill so that it could move forward and be something we can all be proud of.

Through the—through that process, I have come to appreciate how big a challenge this is. After all, TSCA's own fatal flaws have not been fixed in decades. Nevertheless, I believe we are up to the challenge.

Here are the big three issues with the current Senate bill that we are working on. Number one, ensuring that the EPA will have the tools it needs to protect citizens from dangerous chemicals, and to ensure that EPA will be able to review the known 84,000 chemicals. This means getting the prioritization and deadlines right, along with specifically protecting vulnerable populations. Second, we must make sure to protect private rights of action, to hold companies responsible, and ensure they don't cut corners. As a subcommittee chair and supporter of justice for victims, it is not my intent to preempt private claims. That has been stated publicly by myself and by Senator Vitter. Further changes are absolutely necessary to make this intent clear throughout the bill. And finally, we must make sure to protect the right of States to safeguard our citizens.

On that last point, let me take a moment to say to Ranking Member Waxman and members of the California delegation that the chair of our committee, Barbara Boxer, has been a tireless advocate for the State of California and our country. I appreciate the leadership she has shown to protect citizens from dangerous chemicals, and I believe that California and other States play a critical role in lifting up health and safety standards for our country.

As this committee proceeds on its own deliberations of how to reform TSCA, I would word—urge you to work together as we are working together, and I am sure you will. I think it would benefit us all to work together on a bipartisan and bicameral basis. TSCA has been a failed environmental law for decades. We have a historic opportunity before us. Success is far from certain, but it would be a shame to waste it.

And thank you again, Chairman Shimkus. Pleasure to be over here with my former colleagues, and we look forward, Senator Vitter and I do, on working with you on this piece of legislation.

Mr. SHIMKUS. I want to thank you both for coming over. We appreciate the efforts you have made so far, and really the bipartisan approach is going to be critical in moving anything, and we look forward to working with you as we move through this process. So thank you again. You are dismissed, and we will then seat our second panel.

So, as stated in my opening statement, we would like now to welcome and thank you for coming, the Honorable Jim Jones. You are—he was the Assistant Administrator, Office of Chemical Safety and Pollution Prevention, with the United States Environmental Protection Agency.

Sir, you have 5 minutes. We are not hardcore on the time. This is a very important issue, and we look forward to your opening statement.

STATEMENT OF JAMES JONES, ASSISTANT ADMINISTRATOR, OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION, ENVIRONMENTAL PROTECTION AGENCY

Mr. JONES. Good morning, Chairman Shimkus, Ranking Member Tonko, and other members of the subcommittee.

Thank you for inviting me to—for the opportunity to discuss reform of the chemicals management laws of the United States.

I think we all agree on the importance of ensuring that the chemicals manufactured and used in this country are safe. With each passing year, the need for TSCA reform grows, and this administration believes it is crucial to modernize and strengthen the Toxic Substances Control Act to provide EPA with the necessary tools to achieve these goals.

EPA is encouraged by the interest in TSCA reform, indicated by the introduction of several bills in recent years, the bipartisan discussions underway, and today's hearing which marks the fourth in a series of hearings on TSCA reform before this subcommittee.

Many stakeholders share common principles on how best to improve our chemicals management programs. EPA is committed to working with each of you and other members of Congress, the environmental community, the chemical industry, other stakeholders and the public to improve and update TSCA.

As you know, chemicals are found in almost everything we use and consume. While they are essential for our health, wellbeing and prosperity, it should be equally essential that they are safe. Compared to 37 years ago when TSCA was passed, we have a much better understanding of the environmental impacts, pathways of exposure and health effects that some chemicals can have, especially on children and other sensitive populations.

TSCA gives EPA jurisdiction over chemicals manufactured, processed or distributed in the United States; however, unlike laws applicable to drugs and pesticides, TSCA does not have a mandatory program that gives EPA the authority to conduct a review to determine the safety of existing chemicals. In addition, TSCA places challenging legal and procedural requirements on EPA before we

can require the generation and submission of data on the health and environmental effects of existing chemicals.

While TSCA was an important step forward when it passed in 1976, it has not only fallen behind the industry it was intended to regulate, it has also proven an inadequate tool for providing the American public with the protection they rightfully expect from exposure to harmful chemicals. When TSCA was enacted, it grandfathered-in, without any evaluation, about 60,000 chemical in commerce at the time.

It has also proven challenging to take action to limit or ban chemicals that have been determined to pose significant health concern. For example, in 1989, after years of study, EPA issued a rule phasing out most uses of asbestos in products. Yet, in spite of near-unanimous scientific opinion, a Federal court overturned most of this action because it found the rules had failed to comply with the requirements of TSCA. In the past 37 years, the EPA has regulated only 5 chemicals under Section 6 of TSCA, which gives the EPA the authority to ban harmful chemicals.

While EPA is committed to using the tools available under TSCA, we believe it should be updated and strengthened to ensure that EPA has the appropriate tools to protect the American public from exposure to harmful chemicals. It is crucial that any updates to TSCA include certain components.

In September of 2009, the administration announced a set of principles to help guide the discussion to update and strengthen TSCA. These include providing the agency with the tools to quickly and efficiently obtain information from manufacturers that is relevant to determining the safety of chemicals. The EPA also should have clear authority to assess chemicals against a risk-based safety standard, and to take risk management actions when chemicals do not meet the standard.

On April 15, Senators Lautenberg, Vitter and others introduced S. 1009, the Chemical Safety Improvement Act. While EPA has not yet developed a formal position on the bill, we offer the following observations in light of the Agency and the administration principles. As stated in the principles, legislation should provide EPA with authority to establish risk-based safety standards that are protective of human health and the environment. The EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of consideration, including children's health, economic costs, social benefits and equity concerns. The principles further indicate that clear, enforceable and practicable deadlines should be set for the Agency to review and make decisions on chemicals, in particular, those that might impact sensitive populations, and provide a sustained source of funding for implementation. Administrative requirements should add demonstrable value to the process beyond existing law and requirements. Legislation should provide the EPA with tools to ensure the protections put in place are carried out, and provide a level playing field for companies that comply.

We understand the concerns raised by many stakeholders regarding the appropriate role for States in addressing the risks of chemi-

cals to which their citizens are exposed, and EPA stands ready to provide technical assistance on this important issue.

Mr. Chairman, thank you again for your leadership on TSCA reform, and I will be happy to answer questions that you or members of the committee have. Thank you.

[The prepared statement of Mr. Jones follows:]

TESTIMONY OF
JAMES JONES
ASSISTANT ADMINISTRATOR
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
U.S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

NOVEMBER 13, 2013

Good morning Chairman Shimkus, Ranking Member Tonko, and other members of the Subcommittee. Thank you for the opportunity to discuss reform of chemicals management in the United States.

I think we all agree on the importance of assuring chemical safety, restoring public confidence in the safety of chemicals used in everyday products, and providing global leadership in chemicals management. The Administration therefore believes it is crucial to modernize and strengthen the Toxic Substances Control Act (TSCA) to provide the EPA with the tools necessary to achieve these goals. With each passing year, the need for TSCA reform grows.

We are encouraged by the interest in TSCA reform indicated by the introduction of several bills in recent years, that bipartisan discussions are occurring, and that hearings on TSCA related issues are being held. For example, today marks the fourth in a series of hearings on TSCA reform before this subcommittee. Many stakeholders share common principles on how best to improve our chemical management programs. The EPA is committed to working with the

Congress, members of the public, the environmental community, the chemical industry, and other stakeholders to improve and update TSCA.

Chemicals are found in most everything we use and consume, and can be essential for our health, our well being, and our prosperity. It should be equally essential that chemicals are safe. Compared to 37 years ago when TSCA was passed, we have a better understanding of the environmental impacts, exposure pathways, and health effects some chemicals can have – especially on children. A strong reauthorization measure would enable us to significantly improve the effectiveness of TSCA.

TSCA gives the EPA jurisdiction over chemicals manufactured, processed, or distributed in the United States. Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory program that gives the EPA the authority to conduct a review to determine the safety of existing chemicals. In addition, TSCA places challenging legal and procedural requirements on the EPA before the agency can require the generation and submission of data on the health and environmental effects of existing chemicals.

TSCA was an important step forward in 1976. But over the years, not only has TSCA fallen behind the industry it is intended to regulate, it has also proven an inadequate tool for providing the protection against chemical risks that the public rightfully expects.

When TSCA was enacted, it grandfathered in, without any evaluation, about 60,000 chemicals in commerce that existed in 1976. The statute includes challenging requirements that the EPA must fulfill in order to compel companies to provide toxicity data needed to address gaps in understanding chemical risks. As a result, in the nearly 37 years since TSCA was passed, the EPA has only been able to require testing on just a little more than 200 of the more than 84,000 chemicals listed on the TSCA Inventory.

It has also proven challenging in some cases to take action to limit or ban chemicals that the EPA has determined pose a significant health concern. For example, in 1989, after years of study and nearly unanimous scientific opinion, the EPA issued a rule phasing out most uses of asbestos in products. Yet, a federal court overturned most of this action because it found the rule had failed to comply with the requirements of TSCA. In the last 37 years, the EPA has regulated only five chemicals under Section 6 of TSCA.[1]

While the EPA is committed to using the tools available under existing law, TSCA should be updated and strengthened, including providing the appropriate tools to protect the American people from exposure to harmful chemicals. It is crucial that any update to TSCA include certain components.

[1] Ban on manufacturing, processing, distribution in commerce and use of PCBs; ban on manufacture, processing, distribution in commerce of fully halogenated chlorofluoralkanes for aerosol propellents; ban on storage and disposal of dioxin contaminated waste at one facility in Arkansas; limit on certain uses of metalworking fluids; and ban on hexavalent chromium chemicals in comfort cooling towers.

In September 2009, the Administration announced the Essential Principles for Reform of Chemicals Management Legislation, attached below, to update and strengthen TSCA. These include that the agency should have the tools to quickly and efficiently obtain information from manufacturers that is relevant to determining the safety of chemicals. The EPA also should have clear authority to assess chemicals against a risk-based safety standard and to take risk management actions when chemicals do not meet the standard. The principles further state that both chemical manufacturers and the EPA should assess and act on priority chemicals, both existing and new, in a timely manner. This means that the EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive populations.

At the same time the principles to update and strengthen TSCA were announced, the agency affirmed that, while the legislative reform process is underway, we are committed to using the current authority under TSCA to the fullest extent to protect human health and the environment.

On April 15, Senators Lautenberg, Vitter, and others introduced S. 1009, the Chemical Safety Improvement Act. While the EPA has not yet developed a formal position on the bill, we offer the following observations in light of the attached principles. As stated in the principles, legislation should provide the EPA with authority to establish risk-based safety standards that are protective of human health and the environment. The EPA should have clear authority to take

risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

The principles further indicate that clear, enforceable, and practicable deadlines should be set for the agency to review and make decisions on chemicals, in particular those that might impact sensitive populations, and provide a sustained source of funding for implementation. Administrative requirements should add demonstrable value to the process beyond existing law and requirements.

To maximize the transparency of the information underlying these safety decisions, legislation should discourage unwarranted Confidential Business Information (CBI) claims. Manufacturers should be required to substantiate their claims of confidentiality. Legislation should provide the EPA with tools to ensure that protections put in place are carried out and provide a level playing for the companies that comply. We understand the concerns raised by many stakeholders regarding the appropriate role for states in addressing the risks of chemicals to which their citizens are exposed, and the EPA stands ready to provide technical assistance on this important issue.

Mr. Chairman, thank you again for your leadership on TSCA reform. I will be happy to answer any questions you or other members may have.

APPENDIX: Essential Principles for Reform of Chemicals Management Legislation

The U.S. Environmental Protection Agency (EPA) is committed to working with the Congress, members of the public, the environmental community, and the chemical industry to reauthorize the Toxic Substances Control Act (TSCA). The Administration believes it is important to work together to quickly modernize and strengthen the tools available in TSCA to increase confidence that chemicals used in commerce, which are vital to our Nation's economy, are safe and do not endanger the public health and welfare of consumers, workers, and especially sensitive sub-populations such as children, or the environment.

The following Essential Principles for Reform of Chemicals Management Legislation (Principles) are provided to help inform efforts underway in this Congress to reauthorize and significantly strengthen the effectiveness of TSCA. These Principles present Administration goals for updated legislation that will give EPA the mechanisms and authorities to expeditiously target chemicals of concern and promptly assess and regulate new and existing chemicals.

Principle No. 1: Chemicals Should Be Reviewed Against Safety Standards That Are Based on Sound Science and Reflect Risk-based Criteria Protective of Human Health and the Environment.

EPA should have clear authority to establish safety standards that are based on scientific risk assessments. Sound science should be the basis for the assessment of chemical risks, while recognizing the need to assess and manage risk in the face of uncertainty.

Principle No. 2: Manufacturers Should Provide EPA With the Necessary Information to Conclude That New and Existing Chemicals Are Safe and Do Not Endanger Public Health or the Environment.

Manufacturers should be required to provide sufficient hazard, exposure, and use data for a chemical to support a determination by the Agency that the chemical meets the safety standard. Exposure and hazard assessments from manufacturers should be required to include a thorough review of the chemical's risks to sensitive subpopulations.

Where manufacturers do not submit sufficient information, EPA should have the necessary authority and tools, such as data call in, to quickly and efficiently require testing or obtain other information from manufacturers that is relevant to determining the safety of chemicals. EPA should also be provided the necessary authority to efficiently follow up on chemicals which have been previously assessed (e.g., requiring additional data or testing, or taking action to reduce risk) if there is a change which may affect

safety, such as increased production volume, new uses or new information on potential hazards or exposures. EPA's authority to require submission of use and exposure information should extend to downstream processors and users of chemicals.

Principle No. 3: Risk Management Decisions Should Take into Account Sensitive Subpopulations, Cost, Availability of Substitutes and Other Relevant Considerations

EPA should have clear authority to take risk management actions when chemicals do not meet the safety standard, with flexibility to take into account a range of considerations, including children's health, economic costs, social benefits, and equity concerns.

Principle No. 4: Manufacturers and EPA Should Assess and Act on Priority Chemicals, Both Existing and New, in a Timely Manner

EPA should have authority to set priorities for conducting safety reviews on existing chemicals based on relevant risk and exposure considerations. Clear, enforceable and practicable deadlines applicable to the Agency and industry should be set for completion of chemical reviews, in particular those that might impact sensitive sub-populations

Principle No. 5: Green Chemistry Should Be Encouraged and Provisions Assuring Transparency and Public Access to Information Should Be Strengthened

The design of safer and more sustainable chemicals, processes, and products should be encouraged and supported through research, education, recognition, and other means. The goal of these efforts should be to increase the design, manufacture, and use of lower risk, more energy efficient and sustainable chemical products and processes.

TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety.

Principle No. 6: EPA Should Be Given a Sustained Source of Funding for Implementation

Implementation of the law should be adequately and consistently funded, in order to meet the goal of assuring the safety of chemicals, and to maintain public confidence that EPA is meeting that goal. To that end, manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.

Mr. SHIMKUS. Thank you. Now I will recognize myself for the first 5 minutes for the starting of questions.

So, again, welcome.

Does Senate Bill 1009, in your opinion, strengthen EPA's ability to prevent dangerous new chemicals or those with inadequate information from entering the market?

Mr. JONES. Yes, Congressman. To clarify, the existing statute does not require EPA to make an affirmative finding of safety for a new chemical, as 1009 requires an affirmative finding on the part of the EPA before a new chemical can enter the market. As it relates to data generation, interestingly, my attorneys have read the bill to provide EPA with the ability to require the generation of data if necessary to make a finding.

There are other stakeholders who are not reading that provision the same way, which to me is an indication that there may be a need for clarification around that.

Mr. SHIMKUS. Thank you. Do you consider Senate 1009 an improvement over current law for EPA to address hazards and risk of chemical substances in American commerce?

Mr. JONES. So, you know, as we heard from Senator Udall, TSCA is perhaps one of the most poorly implemented environmental statutes, and so the way in which we look at the bill isn't is it better, is it—does it allow us to achieve our stated objectives of safe chemicals in the United States. And in that respect, under that standard, which is the way I am attempting to look at it, I think that there are some shortcomings, as we heard from Senator Vitter, that I would be happy to talk about as well.

Mr. SHIMKUS. Many witnesses have testified before our committee on the strengths and successes of existing TSCA, Section 5, provisions for new chemicals, and new uses of existing chemicals. Notwithstanding Senate 1009 makes changes to Section 5, do you consider these changes appropriate?

Mr. JONES. I think it is surprising to most people that we do not need to affirmatively determine safety before a chemical enters the market, so I think that that change is an important one, that the Agency affirmatively say, yes, this chemical is safe before it enters the market.

Mr. SHIMKUS. Could these changes negatively impact innovation in the United States?

Mr. JONES. When people talk about innovation, which we are very sensitive to at EPA and try to facilitate it, I don't think they think of it as innovation of unsafe things. So I don't view a requirement that the Agency affirmatively determine something meets a safety standard as impacting innovation in a negative way. I actually think it will facilitate innovation, because innovation should be around safe things.

Mr. SHIMKUS. Right. I appreciate that. Further, some witnesses have talked about EPA needing more information on chemicals. Section 4 of Senate 1009 provides the EPA authority to order development of data and information on chemicals. Is this a tool the Agency currently has under Section 4 of TSCA today?

Mr. JONES. Thanks, Mr. Chairman. That is actually one of the real highlights of the introduced bill. Right now, the Agency, if we wanted a company to generate health and safety data for a chem-

ical, we need to go through a rather complex rule-making process, which also requires us to make certain findings that creates somewhat of a catch 22. We have to have a sense that there is a problem before we require the generation of this data, and the rulemaking themselves can take up to 5 years, if not longer.

So order authority, the ability to, without going through that elaborate process, is a huge improvement, and it is an authority that we have in our pesticides program right now.

Mr. SHIMKUS. And you answered it in the last question—the prepared questions I have is, order authority would be helpful in this venue, as you just testified.

Mr. JONES. Very much so.

Mr. SHIMKUS. Let me ask two other questions based upon your opening statement.

When you say equity concerns, what do you mean?

Mr. JONES. So sometime, well, actually, whenever you are protecting in a regulatory decision, or otherwise, it is important to understand where the protections occur. It is also important to understand where do the costs fall. Are the costs being borne by a broad segment of society, a narrow segment of society, are the benefits being enjoyed by a very narrow segment of society, or a broad segment of society? And so it is understanding where the costs and the benefits of a decision may fall. Understanding what they are.

Mr. SHIMKUS. We kind of need a little more work on that because I think, for me, the basic premise is are we producing chemicals that are safe. So that I would think a safe chemical would be good for everybody in the production process and for the consumers, but I will get more briefings on that.

When you define sensitive populations, what do you mean by that?

Mr. JONES. Well, so that can be an equity concern. So that by looking at what we expect that we are going to be looking at highly-exposed individuals, wherever they may be——

Mr. SHIMKUS. In the workplace or——

Mr. JONES. In the workplace——

Mr. SHIMKUS [continuing]. Outside the fence of the facility, is that what we are talking about?

Mr. JONES. Whoever is highly exposed to the chemical that we are looking at, or the use that we are looking at. And we also mean it to include are there certain parts of the population that may be biologically more sensitive. So a child or an infant may have different sensitivities than an adult, an elderly individual may have different sensitivities than a teenager. And so we look at both the highly exposed, who is getting more exposure than the average, and are there individuals or groups that may have greater sensitivity than the average.

Mr. SHIMKUS. Great. Thank you very much. My time has expired. The Chair now recognizes Mr. Tonko for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair, and thank you, Administrator Jones, for your guidance.

Now, the American people have relied on EPA and the Toxic Substances Control Act to protect them against the dangers of toxic chemicals, but EPA has faced significant challenges in banning or restricting toxic chemicals under TSCA, even in cases where the

risks are widely recognized and understood, such as is the case of asbestos. So EPA's first principle of TSCA reform from 2009 reads, and I quote, "chemicals should be reviewed against safety standards that are based on sound science, and reflect risk-based criteria protective of human health and the environment."

Some have suggested that EPA should consider the cost to the chemical industry and others when setting a safety standard. That would mean that somehow EPA would have to factor in the cost of reducing the public's exposure to harmful chemicals when determining whether exposure to a chemical is safe.

Would an approach that requires consideration of cost and determination of the safety standard comport with EPA's principle?

Mr. JONES. Thank you, Representative Tonko. The administration principles speak both to science-based safety standards, and then in risk management, the Agency having the flexibility to consider other factors such as costs, so that when we are looking at how to mitigate a risk, those cost considerations can play into the ultimate decision making. And those concepts are both captured in the administration principles.

Mr. TONKO. So based on science and cost?

Mr. JONES. That is right.

Mr. TONKO. We are looking at both. Historically, TSCA has applied an unreasonable risk standard. This standard has been interpreted to require cost consideration in setting standards, and it was one of the key problems that led to the tragic failure to phase-out use of asbestos. Is that correct?

Mr. JONES. I think that not just in the unreasonable-risk standard itself, but many of the other requirements within Section 6, including the least burdensome requirement. Those two phrases, and a lot of other language around it, required what I would consider to be paralysis by analysis. So much analysis, you could never actually finish the work. And those conspired to get in the way of EPA in the asbestos context, and I would argue since then of being effective with Section 6.

Mr. TONKO. So the bill we are considering today continues to use the legal standard of unreasonable risk. I am concerned that continuing to use this standard invites the use of the traditional interpretation which leaves EPA, as you made mention, paralyzed. Is this a fair concern?

Mr. JONES. It is interesting, Congressman. There are a number of people in the stakeholder community, and they—in my conversations, they don't fall out in terms of, you know, one group versus another, but there are some parties who believe unreasonable risk can only be read to mean a cost benefit balancing. There are others who believe that it is all of the language around it that will matter ultimately. And so I think it is important to have that dialog to come to consensus so everyone agrees, whatever words are being used, there is a common understanding.

That being said, I do believe that 1009 also has other language in it, beyond unreasonable risk, that has a similar effect as the least burdensome requirement which requires a seemingly endless amount of analysis on the part of the Agency before we can ever move forward. So I think that that is important to address as well.

Mr. TONKO. And so in your view, we could end up with an adequate standard if we make it clear that EPA should abandon the historical interpretation of unreasonable risk?

Mr. JONES. You know, I—interesting—I fall within the camp, thinking that the statute can clearly define unreasonable risk, but you need to use enough words that you counter the case law that exists out there right now, and the way in which the term is used within existing TSCA, but it is very important that whatever is done, that people agree about what the interpretation is, and not be in a position where people look at the same two words and think it means two different things.

Mr. TONKO. So would it be easier to simply use a new standard that doesn't have the baggage associated with the phrase unreasonable risk?

Mr. JONES. Well, that would be one way to do that.

Mr. TONKO. OK. Given the history of litigation under TSCA, statutory language on cost consideration and the safety standard must be completely clear. I commend the administration for its clear principle on this matter, and look forward to ensuring that any bill we produce is consistent with the administration's position, otherwise we will have a lot of explaining to do to the victims of asbestos and other toxic chemical exposure.

There is also a lot of talk about resources, as you talked about putting more and more into the standards that need to be met and reviewed. In your opinion, where are we at with the resource issue in order for the Agency to comply with the implementation?

Mr. JONES. So one of the administration's principles is that there be a sustained source of funding for the EPA. Under existing funding, we would be limited in how much progress we could make in any period of time. We would think that a sustained source of funding would involve something above and beyond what currently exists for EPA. I think there are some models out there we could look to.

Mr. TONKO. Thank you very much, Administrator Jones.

Mr. JONES. Thank you.

Mr. SHIMKUS. Gentleman's time has expired. Chair will now recognize the gentleman from Georgia, Mr. Gingrey, for 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you.

Administrator Jones, I have got—actually I have got four questions for you, and I will start.

Were Senate Bill 1009 enacted tomorrow, what would be the status of the regulations or guidance under current law? Would EPA need to reissue new regulations for regulatory matters that are already settled under current law?

Mr. JONES. Thank you, Congressman.

So I believe that existing regulations would carry on as they are. I think guidance, we would need to look case-by-case to each guidance to see whether or not a new law, such as 1009, would require us to make any modifications to conform with a new statute. But regulations would carry on as they are currently drafted.

Mr. GINGREY. Great. Thank you. And the second question, how could activities currently underway at EPA, as an example, identification of work plan chemicals and progress in conducting risk as-

sessments of them, be integrated into S. 1009 in a manner that does not disrupt or delay current TSCA work?

Mr. JONES. I believe that the existing—introduced Bill 1009 allows the agency to designate the compounds that we are already working on, workplan chemicals and other chemicals for which we have prioritized, which are about 80-plus, as high priority right from the get go. So right from the beginning, they would become high priority chemicals under the current draft.

Mr. GINGREY. In your view, does the knowhow, experience and capability of the United States in regulating chemicals compare to other nations?

Mr. JONES. Yes, well, just so you understand, my experience includes about 20 years working in the pesticides program and then in this capacity as well. Pesticides are chemicals and, in the pesticide context, we have a very strong statute that requires us to evaluate every chemical and have been able to effectively do that, so I think we have some of the best knowhow, experience and knowledge in the world as it relates to chemicals. I think what we are struggling with in this context is a statute that makes it difficult to apply that experience to the chemicals under TSCA.

Mr. GINGREY. And my last question, and I have got, gosh, 2–1/2 minutes, I may be able to yield back some time.

The United States is currently exploring a free trade agreement, as you know, with the European Union. Do you see any potential impact of those trade talks on domestic chemicals regulation?

Mr. JONES. That is a very good question. What I would say about that is that my organization and myself will participate with USTR, largely through USTR, on those kinds of discussions. What we try to do at EPA is to identify areas where there may be unnecessary barriers to trade, while ensuring that existing health and safety standards in the United States are maintained.

And so sometimes you may identify a barrier, but it is not going to get changed because we have domestic laws that would prevent it, but there are times when you can identify a problem that can be harmonized without changing the domestic safety standards in the United States.

And so that is the sweet spot that we are looking for. Whether we will find any in that context is, I think, too early to determine, but that is how we will approach the issue.

Mr. GINGREY. Could this free trade negotiation influence chemical risk assessment policy in the United States and should it? I mean that is really the meat of the question. They do things differently, obviously.

Mr. JONES. Yes, that is a very good question. The Obama administration has been very clear that we are taking a risk-based approach to chemicals management in the United States. That is what we do under existing law, it is what we are advocating in a reformed TSCA. I don't see any scenario where we would move away from that. It is a pretty core principle of the administration. It has also been the principle of the U.S. Government for many administrations.

Mr. GINGREY. Well, that is——

Mr. JONES. I think it would be kind of unusual for us to move away from that.

Mr. GINGREY. That is very reassuring, Administrator Jones.

Thank you very much, and I yield back 30 seconds.

Mr. SHIMKUS. Gentleman yields back the time. The Chair now recognizes the ranking member, full committee, Mr. Waxman, for 5 minutes.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Jones, thank you for testifying today. I would like to explore two issues with you about this bill. One is the issue of deadlines associated with effective Agency action, and the other is preemption of State requirements.

Let us start with the deadlines issue.

You testified that in the last 37 years, EPA has only been able to require testing on a little more than 200 of the more than 84,000 chemicals listed on the TSCA Inventory. That means that not even one percent of chemicals have been tested for safety in nearly four decades.

I think the American people would see this as disappointing. They are counting on the Agency to ensure chemicals are adequately tested, but this history demonstrates that the law is not working the way it needs to.

That is why, in my view, it is critical that legislation to reform TSCA include meaningful deadlines to ensure that chemical reviews are completed on a timely basis.

Does the bill, Mr. Jones, that we are examining today adequately address this issue? Will it ensure that there are meaningful deadlines to address this huge backlog?

Mr. JONES. Thank you, Congressman Waxman.

I don't believe that it does. The bill does require EPA to set deadlines, but it gives us unlimited ability to change those deadlines. So, in effect, I don't believe as a matter of law there are meaningful deadlines in the statute. I will say, as you well know from the Food Quality Protection Act which you had a big hand in, there were very clear deadlines about what EPA had to do. We had to look at all pesticides used on food within 10 years, and during a 10-year period we evaluated them all, actually, 99 percent, and met the deadline——

Mr. WAXMAN. Yes. I am interested in that because this committee passed that bill. In fact, I worked with Chairman Bliley and Chairman Dingell. It was a strong bipartisan-supported bill. It required pesticide residues on food to be safe for infants and children. It included deadlines for hundreds of chemicals to be reviewed. And you are in charge of both——

Mr. JONES. That is right.

Mr. WAXMAN [continuing]. The TSCA issue and the 1996 law. So you have had the experience with deadlines that were very concrete. Did it affect the Agency's implementation of the law?

Mr. JONES. I think it is why we met the deadline. From 1996 to 2006, we met that deadline for 99 percent of the 10,000 food use tolerances in the United States, from 1996 to 2006 under TSCA, which has currently no deadlines. We——

Mr. WAXMAN. Yes.

Mr. JONES [continuing]. Didn't evaluate a single existing chemical during that——

Mr. WAXMAN. Yes.

Mr. JONES [continuing]. Period of time.

Mr. WAXMAN. Well, 400 pesticide chemicals under the Food Quality Protection Act over 10 years have been reviewed, which complies with all the law's deadlines, and I congratulate you for that. At the same time, EPA completed no reviews under TSCA because there were no deadlines. I think that speaks very favorably for putting deadlines in the legislation.

Now, let me turn to the question of preemption. Over the years, many States have acted to protect the public from the dangers of toxic chemicals. They have removed toxic chemicals from consumer products, they have banned developmental toxins from toys, and they have even worked to regulate chemicals that act as powerful greenhouse gases.

Under this bill, Mr. Jones, EPA is required to determine whether a chemical is a "high priority" or a "low priority" for review. And once this determination is made, State rules are preempted. Isn't that correct?

Mr. JONES. New State requirements would be preempted after EPA makes a determination a chemical is a high priority or a low priority.

Mr. WAXMAN. OK. Now, in fact, the California EPA has identified dozens of State laws and regulations that may be preempted under this approach. But determining something is a "high priority" for review is only the beginning of the process. It could take many years for EPA to adequately address a "high priority" chemical. And without meaningful deadlines, we could have important State public health protections preempted while Federal action languishes indefinitely. Isn't that the case?

Mr. JONES. That is correct.

Mr. WAXMAN. The preemption as you see it is only prospectively, so existing laws would not be preempted?

Mr. JONES. There is—I am sorry. There are actually two provisions; one is for existing requirements. Existing State requirements are preempted when EPA makes a safety determination. A safety determination is just our view of the risks of the compound; it is not the regulation of the compound. So you could have an existing State requirement be preempted once EPA has made a safety determination, but before EPA ultimately regulated it.

Mr. WAXMAN. And that could be years.

Mr. JONES. Well, there are no deadlines, so——

Mr. WAXMAN. Yes.

Mr. JONES. Yes, years.

Mr. WAXMAN. Well, thank you very much for your testimony and your answering these questions. I think it drives us to look at this need for a bill with strong deadlines, and get this job done.

Thank you, Mr. Chairman.

Mr. SHIMKUS. Gentleman yields back his time. Chair now recognizes the gentleman from Pennsylvania, Mr. Murphy, for 5 minutes.

Mr. MURPHY. Thank you, Mr. Chairman. Sir, thank you for being here.

First of all, I want to say I am pleased we are having this hearing and moving forward with much-needed debate. There are some important provisions in the Senate bill to protect public health,

while allowing companies to continue to innovate, and I am supportive of the Federal standard rather than the complexity in the 50-State statute. And one issue I want to raise is language in here related to articles. The bill says imported or exported articles will need to say whether they contain high-priority chemicals. This could require an extensive review—applied outside of the U.S. for articles we import, and this could be an extensive burden so it is something we need to look at in the future.

Mr. Jones, a couple of things in your testimony. On page 5, you refer to social benefits. What does that mean?

Mr. JONES. So how the benefits of the action are captured, and as a general matter, they relate to the health benefits that are generated.

Mr. MURPHY. And you mention health too. I just wondered how—is social different from health?

Mr. JONES. As a general matter, I don't think that it would be.

Mr. MURPHY. OK, I wanted to be clear because that means different things to us. So, all right. Also, you referred on page 6 to sound science. Certainly, that is something this committee advocates a great deal. How do you define sound science, however? Is that something that is based upon refereed journals from scientists—respected scientists, is that something that the EPA puts out, is it something that its committees are appointed with political appointees——

Mr. JONES. Right.

Mr. MURPHY [continuing]. How do you determine sound science?

Mr. JONES. The Agency has actually got a fair amount of guidance that it has that describes the characteristics of what we want our science to include, which I would be happy to provide to the committee. As a general matter though, it includes that—we are looking at all the available information, and that we are relying on peer review to help make sure that our assessment of that science holds up.

Mr. MURPHY. I see. Appreciate it, and I hope we can make sure there is wording in the bill that defines that too. Let me ask this then, how long would the EPA take to accomplishing the following tasks in the Senate bill, assuming adequate staffing and funding. This is in S. 1009. First of all, sorting chemicals at the high and low priorities.

Mr. JONES. So the initial cut around that, actually the Agency did before this bill was introduced, and that took several months to identify perhaps the 250 highest priority chemicals. So the sorting activity of finding what we think are the highest priorities does not take that long.

Now, that being said, we were looking at about—a subset of about 1,200 chemicals for which there was a meaningful data set. At the end of the day, we would be required to sort a much larger universe than that, but that being said, the sorting activity itself is one that does not particularly take a long time.

Mr. MURPHY. OK. How long would it take you to complete the first safety assessment?

Mr. JONES. So we think as a general matter, it is about a 2- or 3-year process to be doing a chemical safety assessment, depending on the complexity of the chemical.

Mr. MURPHY. And how about completion of most safety assessments?

Mr. JONES. Well, the numbers we are dealing with here in—under TSCA are so extraordinarily large, which is why I think that efforts to reform TSCA really focus in on and set some priorities so that you are focusing on those things that have the potential to have the greatest risk.

And so, depending on how you want to define most of the chemicals, it would certainly inform how one would try to answer that.

Mr. MURPHY. So then this begs this question, because it is so important that the manufacturers have some important data on this too, but how long would it take you to publish the first regulations imposing restrictions on a chemical?

Mr. JONES. So after having a safety assessment and safety determination, which we think can happen contemporaneously, it would be about 3 years for a final regulation for a chemical that had been assessed.

Mr. MURPHY. And how about deciding restrictions for the most risky chemicals?

Mr. JONES. Well, it is about—the—3 years.

Mr. MURPHY. Three years for—then either way?

Mr. JONES. Yes.

Mr. MURPHY. Can you elaborate a little bit what would go into that, making these determinations about your regulations of the most risky chemicals?

Mr. JONES. With respect to what is the assessment like, or how do we ultimately determine whether risk management is necessary?

Mr. MURPHY. Maybe what the assessment is like.

Mr. JONES. So the assessment is basically we are going to look at all of the data that is available around hazard, whether the chemical elicits some kind of an adverse effect in animals. Humans being who we are trying to protect, but it is usually the laboratory animals that...

Mr. MURPHY. Would you have ongoing communication with the manufacturers with this? And I think it is very—it is extremely helpful if you have an open communication, not surprising them, but open discussions, honest discussions as to what the scientific base——

Mr. JONES. In the last year and a half or so, we have begun to do some safety assessments, and we try to make it open and available to everyone. I will say manufacturers tend to participate more than others, but it is open to everyone. And so if they have data that is useful to the safety assessment, they are encouraged to bring it to us——

Mr. MURPHY. OK.

Mr. JONES [continuing]. Make sure that we have it.

Mr. MURPHY. Thank you.

Mr. JONES. So we will——

Mr. MURPHY. I yield back.

Mr. SHIMKUS. Gentleman's time expired. Chair now recognizes the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman, for holding this hearing. It is our fourth on TSCA reform before our subcommittee this year,

and I am optimistic our committee can find a bipartisan path to reauthorization, and we address the concerns of most, if not all, of the stakeholders, and I look forward to the process.

I would like to also thank Senators Udall and Vitter for joining us this morning earlier, as well as Assistant Administrator Jones, for the work they have done to move this issue forward.

Mr. Jones, in your professional opinion, does the safety standard in Lautenberg-Vitter strengthen the EPA's ability to regulate chemicals over the present safety standard?

Ms. JONES. Thanks, Congressman Green. I think that there are some issues with the way in which the safety standard in 1009 is drafted, but the principle one that I see is that it requires a degree of analysis of the alternatives to the chemical that you are focusing on that could find EPA in a potentially an endless analytical loop. So that meeting those procedural requirements of evaluating all of the alternatives, the risks and the benefits of all of the alternatives, may find us in a situation where we can't finish on the chemical that we are focusing on, and that is actually built into the safety standards, so I think that that is the principle problem that we see.

Mr. GREEN. Well, and I know there are a number of other questions. I would hope that we could sit down and work that out because, obviously, the EPA is the enforcement agency, but we want to make sure the law is both easily dealt with, both for everyone involved in it. So I look forward to using our resources together to deal with it.

Are some of the challenging and legal procedure requirements encountered under TSCA, in quoting your testimony, fixed in the Lautenberg-Vitter Bill? If so, were these challenges addressed in 1009?

Mr. JONES. I think that the issue that was most effectively addressed in the Lautenberg-Vitter bill is the inability the agency has had to easily require the generation of health and safety data. I think that has been the aspect of the bill that has most moved the ball forward. As I had mentioned earlier, I think that the removal of the least burdensome requirement that many focus on under TSCA has instead been replaced by a different kind of burdensome requirement, and I think that the deadlines—the lack of deadlines will meaningfully impair the Agency's ability to succeed in the way that I think that the drafters intended.

Mr. GREEN. OK. Do you believe the infants, children and pregnant women, and other vulnerable populations, would be protected more under Lautenberg-Vitter than current law?

Mr. JONES. The Lautenberg-Vitter Bill does require that EPA consider sensitive populations in our safety assessments, which is not required under existing TSCA. It doesn't require us to consider them in our safety determinations or risk management, so there is a movement towards that direction in Lautenberg-Vitter.

Mr. GREEN. Under current law, can you explain what happens when a new chemical comes on the market? Does the manufacturer need EPA OK first?

Mr. JONES. They need us to not say no. So they don't need us to affirmatively say yes, they need us to not say no. And the Lau-

tenberg-Vitter Bill rectifies that by requiring EPA to affirmatively say yes.

Mr. GREEN. OK. And you find—if—do you have to find that a chemical is safe before allowing it on the market?

Mr. JONES. We are not required to make that finding.

Mr. GREEN. OK. Would the Lautenberg-Vitter Bill address that issue?

Mr. JONES. Yes, that is——

Mr. GREEN. OK. How would S. 1009 change current law that protects confidential business information, and I know we have dealt with this on our committee a lot of times. Is it—would it require companies to refresh their requests for information protection?

Mr. JONES. The principle change is that it would allow EPA to share confidential business information with State, local, emergency response officials, which is currently prohibited.

Mr. GREEN. OK. How does it meet—make sure that the government officials, including States, get access to the needed information while still protecting those business secrets from competitors?

Mr. JONES. So——

Mr. GREEN. Is that protected in 1009?

Mr. JONES. That is right. It would require the recipient, the State or local responder, to agree to maintain the confidentiality before receiving the information.

Mr. GREEN. Some of the witnesses that will follow you suggest EPA cannot get information to prioritize chemicals, yet I noticed new Section 4(e)(3)(B) allows EPA to ask the public for information that is reasonably ascertainable. Does that section allow EPA to collect information that is reasonably ascertainable to make prioritized—prioritization decisions?

Mr. JONES. It does, but there is also a provision that allows us to require the manufacturers to generate the data without going through a rule-making activity.

Mr. GREEN. OK. And again, Mr. Chairman, I am out of time but I look forward to us working with EPA and the drafting, and to make sure we know we are all on the same page, literally.

Thank you for your time.

Mr. SHIMKUS. Gentleman's time expired. Chair now recognizes the gentleman from Ohio, Mr. Latta, for 5 minutes.

Mr. LATTA. Well, thank you very much, Mr. Chairman. Thanks for holding this hearing this morning, and thank you very much for being here. We really appreciate your testimony, and the discussion that we are having today.

Just again to kind of—where I am coming from. I represent a district that has 60,000 manufacturing jobs, and it is also unique in that I also represent the largest number of farmers in the State of Ohio. So I have parallel things going on out there. And so when I am out at home and this issue comes up, people really want to know what is happening in Washington, and especially where EPA would be going.

And if I could ask you just a couple of questions real quickly. One is, do you believe that the categories that this bill creates for new chemicals will or could negatively impact specialty chemical manufacturers?

Mr. JONES. The new chemical provisions, Congressman, is that what you are—-

Mr. LATTA. Right.

Mr. JONES. I don't believe so. I believe that we will be able to make decisions in a timely manner under the Lautenberg-Vitter bill on new chemicals.

Mr. LATTA. And again, could you define that timely manner?

Mr. JONES. So the current requirement is that we evaluate compounds within 90 days. If we see a problem, we need to inform the submitter. Under the Lautenberg-Vitter bill, that 90 days remains. We have the ability to extend it by 90 days or two periods of time, but it shouldn't exceed another 90 days. So we are still talking about very short periods of time for our review of new chemicals.

Mr. LATTA. OK. And can you also discuss EPA's confidential business information improvements, and how are those working?

Mr. JONES. So we are working very hard to do what I think of as the government's role as it relates to confidential business information, which is to ensure that we are asking the question, is this claim eligible for confidential business information treatment. Historically, we have been somewhat passive which, if someone had asserted it, we basically would just accept that. We are now doing our part, which is to make sure that an assertive claim actually meets the statutory criteria around that. And over the last several years, we have successfully removed over 1,000 claims that have been made just because they were not warranted by the statute, or the manufacturer, when they went back and looked at their files, they didn't think the claim was necessary anymore. So some of it has been us doing more work, some of it has been us working with the manufacturers to ensure that they were keeping their files accurate related to their CBI claims.

Mr. LATTA. And also when you reviewed the bill, would those improvements be consistent with the bill?

Mr. JONES. Generally, they would be. There is a grandfathering-in of CBI claims that—one that was made before the bill would pass would be considered to be CBI that would potentially impact some of this cleanup effort that I am referring to.

Mr. LATTA. OK. And also, how do you believe the coordination has been between the EPA and the TSCA Interagency Testing Committee?

Mr. JONES. So historically, it has not been particularly active, in that other agencies are not big users of that committee, whereby they are able to ask us to generate health and safety data for their purposes. The bill allows that activity to continue in the future. It would be interesting—I really can't predict how much other agencies would be feeling more empowered to ask EPA to use its authorities to require companies to generate health and safety data for their purposes, but it is definitely an authority in the Lautenberg-Vitter Bill.

Mr. LATTA. OK. And finally, if I could, I know there have been some questions that other members have asked about how you have defined certain words that have—that were in your testimony. On page 4, you talk about that, as stated in the principles, legislation provides the EPA with authority to establish risk-based safety standards. How would you define that risk-based safety standards?

Would you see the stakeholders being involved, how would you see—come to that definition?

Mr. JONES. So we would definitely involve stakeholders in that—I will give a few examples based on implementation of other statutes. The EPA would consider, for a chemical that was a quantified carcinogen, that the calculated risk of that compound not creating more than a 1 in a million chance of increasing cancer risk to be a health-based safety standard, where we have identified in a quantifiable way in that case the level at which we believe is protective, based exclusively on a health and safety consideration. So that would be an example of one. It doesn't mean under this bill we would say that the number, but we would include dialog with stakeholders to say, here is an example, do you think this is the appropriate health-based safety standard? Should it be 1 in a million, 1 in 100,000, 1 in 10 million, before we ultimately came down on what we thought was the appropriate health-based safety standard.

Mr. LATTA. Well, thank you very much. And, Mr. Chairman, I see my time has expired, and I yield back.

Mr. SHIMKUS. Gentleman yields back his time. Chair now recognizes my colleague from Colorado, Ms. DeGette, for 5 minutes.

Ms. DEGETTE. Thank you very much, Mr. Chairman. Mr. Jones, we appreciate you coming today. And, Mr. Chairman, I really appreciate you holding this hearing. We have been hammering away at this for some number of years, and I actually think, with the Senate bill and with this committee's efforts, we may be productive. So, yes, let's keep our fingers crossed.

Mr. Jones, one thing we have been talking about is one of the problems with the current act is that roughly 60,000 existing chemicals were grandfathered-in in 1976, and as you testified, there is no criteria to trigger an independent EPA review of an existing chemical. So under the Senate bill, all the existing chemicals in commerce would be identified and prioritized for further evaluation. I want to talk to you about—a little bit about that this morning.

I think given the number of chemicals that are out there, and the subset of chemicals that are actually used in commerce, we all support prioritizing EPA action that might pose a serious risk, but in order for prioritization to work, EPA needs to have the information to make the informed decisions on how to prioritize it.

So as I understood your answers to Mr. Green's questions, for existing chemicals, if the EPA wants to trigger some kind of a review, they have got to promulgate a rule before they do that, is that right?

Mr. JONES. Under current law, that is correct.

Ms. DEGETTE. Yes, and then under—as what—1009 what would happen would be, as a threshold, the EPA would be directed to review the safety of all existing chemicals in commerce, is that correct?

Mr. JONES. That is correct.

Ms. DEGETTE. And so that sounds good, but if the EPA is going to review all of those chemicals, they are going to need to get a lot of data that they don't currently have. Is that right?

Mr. JONES. That is correct.

Ms. DEGETTE. And so I guess what I want to ask you is, under the current drafting of S. 1009, is there a minimum set of information the EPA will have for each chemical so they can decide how to review and prioritize it for action?

Mr. JONES. We think that we will very likely tailor the data that we are interested in having for a safety assessment based on some of the characteristics of the chemical. So, for example, chemicals that are persistent bioaccumulative and have some toxicity, we would require a lot more data for, health and safety data, than for a chemical which our—the evidence that we have based on models that we used, predicted it as likely to be of lower toxicity. So we would probably tailor the data we would like to see for our assessments based on characteristics that we know.

Ms. DEGETTE. Now, in the bill itself, is there actually any standard set for the data that you would use or obtain, or is—would—are you just left to decide that for yourselves?

Mr. JONES. The bill as drafted gives the Agency quite a bit of discretion as to what data it would want to compel generation of.

Ms. DEGETTE. And does it lay out what criteria the Agency would use to decide which—or—you see what I am saying? It is like there are so many chemicals out there——

Mr. JONES. Yes. It gives the criteria for the order in which we prioritize things as high.

Ms. DEGETTE. OK. Now, S. 1009 also changes the requirements for entry into commerce of new chemicals. It is my understanding that maybe as 80 or 90 percent of new chemical applications currently contain no data on potential impacts to human health. Is that correct?

Mr. JONES. That is correct.

Ms. DEGETTE. So under current law, the EPA wouldn't be making an affirmative decision about a new chemical's safety before it enters the market, is that correct?

Mr. JONES. That is correct.

Ms. DEGETTE. Under S. 1009, the EPA must make a decision about the likely safety of a new chemical, is that right?

Mr. JONES. That is correct.

Ms. DEGETTE. But will the EPA have data about the new chemicals to accurately make the safety determination?

Mr. JONES. So we expect that there will be, for many situations, the models that we use to predict hazard will allow us to make such determination—likely to meet the safety standard determination for many chemicals. There will be some chemicals which, when we use predictive models, they are going to raise enough concerns that we are going to want to see health and safety data generated.

Ms. DEGETTE. OK. Well, I appreciate you—I appreciate that answer, but I am a little concerned because it seems a little bit vague, and I think that is one of the areas of this bill we can really work on, is setting clearly what data the EPA needs to be given for certain classes of chemicals. So I look forward to working with you and also with the committee on those issues.

Thanks.

Mr. SHIMKUS. Gentlelady's time has expired. The chair now recognizes the gentleman from West Virginia, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman, and again, thank you for the—once again continuing this discussion.

Mr. Jones, two questions for you. The first is, will, in your analysis of the Vitter bill, did—will it require an expansion, will it need more FTEs, anything along that line to be able to carry out the new mission?

Mr. JONES. In the absence of additional resources, the number of chemicals we would be able to move through the process will definitely be meaningfully constrained.

Mr. MCKINLEY. Will be what?

Mr. JONES. Meaningfully constrained. The number will be smaller than I think most people would hope.

Mr. MCKINLEY. So the answer to the question, are we going to have—are you going to need more FTEs?

Mr. JONES. It is likely that additional FTE would be necessary to achieve the kind of numbers, I think, that generally people would expect from the Agency.

Mr. MCKINLEY. OK. Secondly, is the—some of the criticism of the existing bill and the Vitter language is about the burden placed on EPA to express the need before they make the request to the companies to fulfill that assessment. Can you share with us the value of why the EPA should make the first step in determining the need?

Mr. JONES. The need for health and safety data?

Mr. MCKINLEY. Yes. Right.

Mr. JONES. So the Agency is pretty well equipped, and we are also coming at it with the simple desire to understand health and safety. So we have got both the—well, largely, we have the scientific expertise to be able to judge whether or not health and safety data is necessary, and what kind to make a safety determination.

Mr. MCKINLEY. So if—again, I—that—be more specific with that. So I am just trying to understand that. So—because some are saying they don't think you should make the first step, the company should provide that chemical and their product data. Do you think it best for you to first make the—make your own analysis to determine that there is still a need——

Mr. JONES. The——

Mr. MCKINLEY [continuing]. Before you ask them to produce it?

Mr. JONES. Yes, I think that we have got a pretty sophisticated way of understanding where we need information and where we don't. And as I was answering the question to Congresswoman DeGette, we are able to do it in a way that is tailored to the chemical and the issues that the particular chemical expresses. And so I think in many ways, it can be the most efficient way for the Agency to identify we need this data but not that data.

Mr. MCKINLEY. OK. And maybe to add one last in the little time I have left. I think I heard it—the question but I wasn't sure I heard the answer again, and that is, with the passage of this, this—you really think that this is an improvement for health safety and for children, pregnant women, we—on and on and on. This is going to be an improvement over what we have now?

Mr. JONES. Well, as I said in answer to the first time that question was asked, that the way in which we are trying to think about

it is does this give us the tools to ensure safe chemicals in the United States, and as I pointed out, I think that there are a number of areas which are meaningful deficiencies that would need to be addressed before we could say that this bill will give us the tools we need to ensure safe chemicals in the United States.

Mr. MCKINLEY. So—and the bottom line here, you think this really is an improvement?

Mr. JONES. I think it needs some improvement.

Mr. MCKINLEY. OK, it still needs to be worked. OK, and I am OK with that, but I just wanted—are we—if it is moving in the right direction to make sure that it is an improvement over what we have now.

Mr. JONES. There are aspects that are moving in the right direction, and there are aspects that are not.

Mr. MCKINLEY. OK. Thank you very much.

Mr. SHIMKUS. Will the gentleman yield? Will the gentleman yield?

Mr. MCKINLEY. Yes.

Mr. SHIMKUS. Let me follow up on just two quick questions.

Part of the 85,000 list of chemicals, there are some that are no longer in commerce or in manufacturing processes, and those—you could be—probably easily drop them off, isn't that true?

Mr. JONES. Well, interestingly, we would have to go through a process to drop them off, and as a general matter, manufacturers, even if they are not making the chemicals, like them on the list because at some point in the future, they want to bring that into their production, for whatever marketing reasons they have, they can do that if it is not on the list.

Mr. SHIMKUS. But under the new law, if passed as-is, they are still going to be looked at then. The whole idea is to get through this list in some time.

Mr. JONES. Under 1009, it actually creates two lists. One is an active list, things that are actively in commerce, and one is an inactive list, things that are no longer in commerce.

Mr. SHIMKUS. Right.

Mr. JONES. Manufacturers can go from inactive to active by noticing EPA.

Mr. SHIMKUS. Let me ask another question. Is there a difference between chemicals that go actually into consumer consumption or handling, versus chemicals that are involved just in the manufacturing process that stays within the walls of a facility?

Mr. JONES. The way in which we evaluate them is very different, but we have jurisdiction over both. We evaluate them very differently. One is, we are looking at the exposures that a consumer would get, and the other, we are going to look at what happens in the workplace to the worker if the worker is exposed.

Mr. SHIMKUS. Great, thank you. And the Chair now recognizes the gentlelady from California, Mrs. Capps, for 5 minutes.

Mrs. CAPPS. Thank you, Mr. Chairman, and thank you, Mr. Jones, for your testimony here and your statement here, and your position at EPA.

Many stakeholders have raised concerns about the need to protect vulnerable populations. That is my concern in talking with you during my 5 minutes. Any system needs modernization. TSCA, I

am sure, can use it too, but an essential component is to really address how vulnerable populations will be affected.

Any reform, for example, of this statute that fails to adequately protect children or pregnant women would be a terrible failure. Vulnerable populations do include infants and children, the elderly, the disabled and anyone living in a close proximity to a chemical facility. The National Academies of Science, in their 2009 report called Science and Decision—Decisions, recommended that vulnerable populations should receive special attention at every stage of the risk-assessment process. S. 1009 makes only two references to subpopulations. Vulnerable populations are not addressed in the safety standard, and are not required to be considered in the safety determination. This strikes me as a glaring oversight. Even using the problematic terminology of this bill, a chemical should not be deemed to meet the safety standard if it poses an unreasonable risk to a vulnerable subpopulation.

So I have a couple of yes/no questions to ask you, because I hope you agree with this. Do you think a chemical that poses an unreasonable risk to a subpopulation should be able to pass the safety standard under a reformed TSCA?

Mr. JONES. No.

Mrs. CAPPS. And to follow up, as a general matter, should a chemical that poses a serious or substantial risk to a vulnerable subpopulation be considered acceptable under a reformed TSCA safety standard?

Mr. JONES. No.

Mrs. CAPPS. Well, I thank you for that. That puts you on the record there. Turning now to the risk-management decisions that will be taken when a chemical does not meet the safety standard under a reformed TSCA.

Mr. Jones, should risk-management actions under a reformed TSCA ensure that unreasonable risks, including those to vulnerable populations, are addressed?

Mr. JONES. Yes.

Mrs. CAPPS. And should risk-management actions under a reformed TSCA ensure that a serious or substantial risk to a vulnerable population should be addressed?

Mr. JONES. Yes.

Mrs. CAPPS. Partly in answer to a previous question—well, let us put it this way: The Senate made some progress in their legislation. Are there some areas that we could improve upon that you would like to highlight in less than 2 minutes?

Mr. JONES. Sure. Thank you for that. And I am only in this position because of the fine education I got at the University of California, Santa Barbara. And thank you for——

Mrs. CAPPS. Thank you very much. That doesn't hurt your standing in my eyes.

Mr. JONES. So we think that the kinds of improvements that are necessary to get this bill to the place where we think it gives us the tools we need to ensure safe chemicals in the United States are along the following. That there need to be meaningful deadlines on the Agency, that the safety standard should be clear and understood by all parties as to being a risk-based safety standard. The kind of analysis that we have gotten bogged down because of the

least burdensome requirements under existing TSCA shouldn't be replaced with additional analysis that does not add a lot of value to the ultimate decision making. And I also think that there needs to be a balanced approach to preemption, which I currently don't think the bill achieves.

Mrs. CAPPS. Thank you. Thank you very much for that summary.

Mr. Chairman, I am a strong supporter of reforming TSCA, in addition to wanting us to pay special attention to this particular witness, just because where he received his education.

I do have some serious concerns about the bill before us today. The Senate language does not require the protection of vulnerable populations in the safety standard or in the risk-management decisions, and I think that is a fundamental flaw that would affect each of us in our congressional districts. Any TSCA reform bill this committee considers should ensure that the most vulnerable among us are protected, and this protection is real and effective. So I look forward to having this committee continue to work on this particular issue.

Thank you.

Mr. SHIMKUS. I thank my colleague. I—just to note that right now, there is no—in current law, there is no vulnerable population comment, but in the Senate bill I think it is listed at least twice. So there is some movement in the—in that direction.

The Chair now recognizes the gentleman from—I am trying to find here, gentleman from Florida, Mr. Bilirakis, for 5 minutes.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it very much. Thank you for holding this hearing as well.

I would like to ask a question. Should Congress require a minimum number of chemicals to be acted on each year?

Mr. JONES. That is a great question, Congressman. The benefits of having a minimum number of chemicals is that you can feel that there is forward progress being made all of the time. The downside to it is that, in the absence of meaningful resources, you can find the Agency in a situation where it can't meet the statutory requirements, or the way in which it does so is to by working on easier chemicals, which is not really, I think, what the objective is of setting priorities, that we would be working on the more complicated, difficult compounds first. So there are definitely some pros and cons to including a minimum number of chemicals.

Mr. BILIRAKIS. OK, thank you. Some question that Senate Bill 1009 does not require adequate data to prioritize chemicals. Does Senate Bill 1009 give the EPA authority to seek additional data and info? How do you read Senate Bill 1009?

Mr. JONES. So that is a good question as well. I think that there is a disagreement amongst some of the people reading the bill as to whether or not we have the ability to require the generation of health and safety data if it is not already a high priority chemical. We read the bill to allow us to be able to do that. I think the fact that there are people reading the same words and coming to a different answer to that question is another example where it might be useful to seek clarity on that point.

Mr. BILIRAKIS. All right, thank you very much. Next question, would Senate Bill 1009 allow the EPA to assess the safety of chemicals that are persistent bioaccumulative and toxic, and re-

quire risk management for those that fail to meet the safety standard?

Mr. JONES. The bill allows the Agency to do that, but—not create the explicit requirements to give any priority to persistence or bioaccumulation, but it certainly allows the Agency to evaluate them and take risk management if warranted.

Mr. BILIRAKIS. Thank you. Thank you for your response.

And I yield back.

Mr. SHIMKUS. Gentleman yield to me——

Mr. BILIRAKIS. Yes.

Mr. SHIMKUS [continuing]. For a quick—so risk is defined as hazard plus exposure. Is that how you define it?

Mr. JONES. Hazard times exposure. Yes, hazard times exposure.

Mr. SHIMKUS. So define for me the difference between substantial and unreasonable. So if you have substantial risk, OK, we know what risk is, we know what unreasonable risk, so what are—I guess that is two adjectives, but I mean what is the difference between those two?

Mr. JONES. I actually think it really depends on all of the other words that are used in the statute to describe what the Agency is required to find. I don't believe unreasonable risk, those two words by themselves, mean that the Agency has to conduct a cost benefit analysis. I do believe the courts have said those words used in conjunction with a lot of other words create the requirement of a risk benefit balancing, but the words themselves I don't think mean, to the layperson or anybody who can read the dictionary, means cost benefit. But it is a lot of the words that are used in conjunction with the actual standard that, I think, gives it its full meaning.

Mr. SHIMKUS. Great, thank you. The Chair now recognizes the gentleman from California, Mr. McNerney, for 5 minutes, who has been waiting very patiently.

Mr. MCNERNEY. Waiting and listening, Mr. Chairman. Thank you.

Mr. Jones, in your testimony, I believe you stated that S. 1009 requires affirmative standards. Would you please elaborate on that, especially regarding enforcement, how those affirmative standards would be enforced in the new law?

Mr. JONES. Thank you. That comment reflects specifically to the new chemicals provision in 1009. Under existing law, the Agency, when a new chemical is submitted, we have 90 days to evaluate it, and only if we identify a problem are we able to work with the manufacturer to prevent it from being introduced into commerce. Under S. 1009, it requires the Agency to make an affirmative finding of meeting the safety standard before the manufacturer can move that chemical into commerce.

Mr. MCNERNEY. OK. That is a good thing, I think.

Mr. JONES. I would think so, yes.

Mr. MCNERNEY. You also stated that in S. 1009, the language would make it as difficult as the unreasonable risk or least burdensome language in TSCA to enforce rules as it has been for TSCA with asbestos. Can those—can that language be modified in your opinion to remove some of those barriers, and make it reasonable to enforce?

Mr. JONES. For any of the issues that we have identified, the devil is always in the details, but I think that changes could be made in a way that would not send us into an endless amount of analysis before we could ultimately make protective decisions.

Mr. MCNERNEY. Well, who would you recommend that the committee consult with on that language?

Mr. JONES. I think it is important to have all stakeholders. I mean obviously you can't have literally all stakeholders, to be bringing all people to the table, as I think you get the best outcome and you can get a common understanding of what—the words you are using are the words everybody believes that they mean.

Mr. MCNERNEY. OK. Well, to change the subject a little bit. The European Union has made significant progress on some of the 60,000 chemicals that have been grandfathered. Is that correct?

Mr. JONES. The European Union, which has a very different model, has definitely made some progress in the universe of chemicals sold in Europe.

Mr. MCNERNEY. Would S. 1009 allow you to—the EPA to collaborate with the European Union on identifying some of those, and classifying some of those chemicals?

Mr. JONES. We definitely would be able to collaborate. I think the fundamental problem we and the Europeans are dealing with as it relates to that collaboration is they have required manufacturers to generate a lot of health and safety data, and the European Union under their rules cannot share that information with us. They have to have the company's permission. The companies find themselves in a situation where they negotiated agreements across multiple companies, and unless everybody agrees, they can't give us the information. And so I am hard-pressed to know what U.S. domestic law could do to actually break that log jam. I think we have to——

Mr. MCNERNEY. OK.

Mr. JONES [continuing]. Work something out, not under law, but with manufacturers to figure out how to get access to that treasure-trove of health and safety data.

Mr. MCNERNEY. OK. That is a good answer. Regarding resources, if S. 1009 becomes law, would the Agency need greater resources to carry out the various rule makings laid out in the bill?

Mr. JONES. I think where we would run into issues with expectations, expectations of, I assume, the Congress and certainly I think of the American public, is that the number of assessments we would be able to do under existing resources would probably, for most people, be considered to be inadequate. So to change that, we would need resources. I do think there are models out there that involve the industry financing that are used in the FDA and our pesticides program that are worth looking at.

Mr. MCNERNEY. So in S. 1009, there aren't any dedicated funding sources?

Mr. JONES. No, there are not.

Mr. MCNERNEY. So that could be interpreted as one of the weaknesses in that law—in that proposed law?

Mr. JONES. One of the administration principles is there be a sustained source of funding, and that is not addressed in the bill.

Mr. MCNERNEY. OK, thank you.

Mr. Chairman, I yield back.

Mr. SHIMKUS. Gentleman yields back his time. The Chair now recognizes the gentleman from Pennsylvania, Mr. Pitts, for 5 minutes.

Mr. PITTS. Thank you, Mr. Chairman.

Mr. Jones, in our first hearing, witnesses stated that EPA needed specific statutory authority for chemical prioritization. Is that important?

Mr. JONES. Thank you, Congressman. I think it is important because there are so many chemicals in commerce that it is important to direct the Agency to focus on those that may present risks earlier in the process rather than later. And in the absence of that, you could see wily bureaucrats, of which I am one, working on easy things because we can do a lot of easy things. So I think being directed to work on those things that are the highest priority is a very important thing when you have a universe that big.

Mr. PITTS. Does S. 1009 require that chemicals be prioritized?

Mr. JONES. Yes, it does.

Mr. PITTS. Does S. 1009 allow EPA to consider potentially vulnerable subpopulations in making decisions to prioritize chemicals for review, and in subsequent safety assessments and determination?

Mr. JONES. In safety assessments, we are required to consider vulnerable populations. That is not required of safety determinations or—in the priority setting. We are not prohibited, but it is not required for the other two.

Mr. PITTS. S. 1009 lays out framework requirements for prioritizing existing chemicals, gathering, testing data and information, conducting safety assessments and making safety determinations. Does a reformed TSCA need to set these requirements out as four separate steps?

Mr. JONES. The bill has a lot of what we were referring to as framework requirements, we think we counted a total of about 17. I think it is possible to collapse a number of the frameworks down, and not lose some of what the drafters intended. Most were drafted—making it more streamlined and straightforward.

Mr. PITTS. S. 1009 has provisions requiring that EPA sort chemicals for review as either a high or low priority. Should there be more categories than just high or low priority?

Mr. JONES. I don't see a huge amount of value in adding another category other than high or low.

Mr. PITTS. Are you concerned that you cannot seek judicial review of the prioritization screening decisions?

Mr. JONES. That is a very good question. I think it runs counter to generally how we run the government, that an Agency action that ends all other downstream consequences is unable to be challenged. So a high-priority decision—when we do that, downstream things have to happen. And so it doesn't bother me that that is not subject to judicial review, because the downstream thing ultimately will. A low priority under 1009 actually stops all action. EPA at that point is done. No more work. Stop. That to me is a final Agency action, and although I would like to think all of our final Agency actions shouldn't be—no one should be bothering us about them, I—as a matter of good government, I think that it is important to allow people who disagree with a final Agency action to seek review

of that in an appropriate judicial proceeding. And so I think that having a law not be subject to judicial review is not a good place for the government to be in.

Mr. PITTS. And managing the many chemicals that you need to review, how long do you expect this process to take, both to prioritize and schedule for assessment?

Mr. JONES. The prioritization process I think will happen, the initial one, very quickly. The initial assessments will happen within a couple of years. I think it will be many years before we have evaluated all the high priority chemicals.

Mr. PITTS. OK, thank you, Mr. Chairman.

Mr. SHIMKUS. Gentleman yields back his time.

Chair now recognizes the gentleman from Louisiana, Mr. Cassidy, for 5 minutes.

Mr. CASSIDY. Mr. Jones, I apologize if someone else has asked. I had to step out.

To prove safety by the first—to prove that something is not at risk, you have to prove a negative. It is very difficult to prove a negative. How do you prove a negative?

Mr. JONES. So we rely on analytical tools that often include data, often include models. So if something does not express hazard, it is impossible for it to have risk, if something doesn't——

Mr. CASSIDY. Now, that is—now, let me ask, because we had a hearing about the risk of something for breast cancer. It is a big concern of mine. My wife is a breast cancer surgeon, and I am a physician, so we were on a vacation so we pulled down the literature, and there is a body of literature for this particular chemical, that it could cause breast cancer, but—and somebody did a regression analysis and goes, you have got to be kidding me. There is obesity, alcohol, cigarette use, family history, and here is a very marginal effect that may or may not. But the witness was passionately and quite emotionally declaring that this particular chemical had an impact upon breast cancer.

So I guess I would come back to no risk at all may be in the eye of the beholder, right, or of the interest group or whatever. In that situation, what does this law allow you to do?

Mr. JONES. Well, it would require us to assess the risk of that chemical, and make a determination as to whether or not that risk met a safety standard.

Mr. CASSIDY. I guess what I am after, the safety standard seems a nebulous thing to me.

Mr. JONES. So—yes.

Mr. CASSIDY. And so, again, this advocacy was just so passionate in their emotion, even though the retrogression analysis showed that the effect was nonexistent or minimal, if it existed. It just couldn't be teased out. So would that—would this nebulous standard say, listen, best science shows that it is obesity, family history, alcohol and cigarettes. This marginal effect we can't prove so we move on, or we just say, no, we have to say this is not safe?

Mr. JONES. We have a pretty long record of how we calculate risk, and what we view to be risks that are beyond negligible. They involve using standards such as the increased lifetime cancer risk of a substance, they include calculations that we use for other kinds of effects where we look for a certain margin of exposure be-

tween the exposure level and when adversity occurs, and there is a general understanding about how we——

Mr. CASSIDY. So I think, I gather, that industry would be able to look at a basically kind of common-law standard, if you will, something that this—it isn't nebulous, you are telling me, but there is something they could look at and say, below this threshold, we know we are OK?

Mr. JONES. That is correct.

Mr. CASSIDY. Then let me also ask, I was struck once in some hearings we had that the EPA's current method of analysis does not take into account a threshold effect, that they extrapolate all the way down, if we know this level really causes damage, but we know at this level it is in the environment, and common exposure doesn't cause damage. I am a doc, aflatoxin is a great example of something we are all exposed to, but it is only above the threshold has a problem, EPA, as I gather, does not take that into account.

Mr. JONES. The vast majority of the chemical assessments we do are based on the threshold model that you are describing. A relatively small number, in particular, those that are carcinogens, where there has not been demonstrated the threshold that you are describing, we use the model that you are describing. That is a relatively small number of chemicals.

That being said, we have gotten some advice from the NAS to begin to think about how to use models other than the threshold model that I just described. But right now, the vast majority of chemical assessments that we do rely on the threshold model that you are describing.

Mr. CASSIDY. OK, I had a little bit of a different impression, so I am reassured regarding that.

The subpopulation groups also seem to be something which is, you know, going to be difficult to define. I know that there are always two or three standard deviations out, somebody with a genetic predisposition to, fill in the blank. And it may be an environmental exposure will fill in the blank. You with me? Take type 1 diabetes.

Mr. JONES. Um-hum.

Mr. CASSIDY. There seems to be a genetic component, but some interaction with the environment. How would you ever—it almost seems like if you really chase that out, you are always going to find some subpopulation with a genetic exposure which, combined with the environmental, is problematic.

I know you have thought about this. What are your thoughts?

Mr. JONES. So there are either a couple of things that we have—I like to give the example of what we have done in our pesticide program, which is a similar requirement around significant, highly exposed and vulnerable populations. We have literally identified the populations that we look at in terms of age, and we look at children at six-month intervals when they are very young, and then we go to 1-year intervals, and then we go to, you know, women of childbearing age and those over 50. And we also do it by race and ethnicity. And so we have defined them, we have taken comment on that, and it is then widely understood here are the populations below the general population that we are going to look at for every assessment that we do.

I would expect that we would do something similar here. They may not be the exact same subgroups that we would look at, but we would go through a process of identifying them and asking the public to give us feedback on it. The other thing is that we, as a general matter, use an uncertainty factor to capture the general variability within the population as it relates to intraspecies sensitivity.

So that tenfold factor we use to try to broadly capture that phenomenon. When there is information that leads us to believe that for a specific effect, something beyond that 10 is necessary, then we use that to inform our assessment.

Mr. CASSIDY. I will finish by saying your testimony is very reassuring, but I remember reading the National Academy of Science's report on your formaldehyde report, and they really felt like the conclusions of the report were not based—were not supported by the data which had been amalgamated, thinking specifically of tumors in the nasal laryngeal area in rats, and yet EPA kind of swore by it.

So thank you for your testimony, and I yield back.

Mr. SHIMKUS. Don't you hate these real smart members of Congress who ask these—make us all look bad?

So last but not least, my colleague from the great State of Georgia, Mr. Barrow, for 5 minutes.

Mr. BARROW. Thank you, Mr. Chairman. Thank you, Mr. Jones, for being here today.

I know that the EPA hasn't yet taken a position on S. 1009 all together—in its all together, but I want to see if we can't draw some comparisons between current law and the proposal, and just get some idea where we can find some—for example, are there any areas of the bill that, in the opinion of the EPA, are better than current law?

Mr. JONES. Yes. Mandating the Agency evaluating existing chemicals is a non-trivial improvement over the existing law. That is not something we are required to do right now. Giving the EPA the ability to require manufacturers to generate health and safety findings, using order authority, is dramatically more efficient than the process that we have under the existing law. And then the requirement that EPA make an affirmative finding for a new chemical before it enters commerce, I think is also a pretty significant improvement.

Mr. BARROW. Flipside, any areas of the proposed legislation that in your opinion are worse than current law?

Mr. JONES. Yes, I will say that the preemption provision is dramatically less—I think at the end of the day would be less protective than the current preemption under TSCA.

Mr. BARROW. I am kind of reminded of Lincoln's comment about liberty, you know, the sheep praises the shepherd for driving the wolf away from his neck, and the wolf condemns him for the same act. Clearly, we need a new word of liberty, you know, new agreement on what it means. So I want to talk about protection in this context, the interplay between Federal and State regulations that is a real major policy issue we have to deal with.

One concern that I have is if funding for the big regulator, the national regulator, the EPA, is either chronically inadequate so

that the regulator is malnourished, or is highly sporadic as a result of politics, ranksmanship and shutdown or what have you. The concern I have is whether or not we will have effective regulation if we preempt State, and the only regulator who is left on the scene is unable to do his job. I have a concern about that, but I also have a concern about, you know, the regulator wanting to do its job. You know, a regulator that doesn't want to do its job is like going bird hunting and having to tote the dog. But a regulator that can't do its job is like going bird hunting without the dog. I am not sure which is better. Each is equally ineffective as far as the customer and the taxpayer is concerned.

So help me understand, in your experience, what has been the benefit of the current regime of dual State and Federal regulations on the one hand, and what has been the cost of the current regime, and how would you suggest we go forward?

Mr. JONES. I think the benefit is a good part of why we are here; that because the Federal law is ineffective, States have stepped into the breach and have been doing the work necessary to protect the people in their States, which has created an incentive on the part of the industry, in my view, to raise the bar of the Federal law so that States don't feel compelled to step into the breach, because the Federal Government is ensuring the safety of their citizens. I think that is the——

Mr. BARROW. You described the ideal or optimal role of the State regulator as being a pride toward better action, better regulation nationwide is how you describe it.

Mr. JONES. Um-hum.

Mr. BARROW. As being basically a driving force for getting——

Mr. JONES. I think that they have been the driving force in the chemical space that has been basically the only regulation.

Mr. BARROW. Aren't you—don't you share the concerns though of others though that if you do have a nationwide standard, if the regulator is malnourished or underfunded, that that could be a problem as well, they can't keep up with the demand? So you don't want to replace something bad with something that——

Mr. JONES. No, exactly.

Mr. BARROW [continuing]. Does not exist.

Mr. JONES. It is a challenging dynamic that you are trying to ultimately achieve, where the absence of action on the Federal Government doesn't mean nobody gets protected, that it keeps—the potential threat of that happening keeps people like me on top of our job, moving the ball forward, which also creates the dynamic where the States feel like they don't feel like they need to regulate because it is going to be taken care of at a national level. And I think that is very——

Mr. BARROW. We should understand—you can understand that even if you are doing a good job at the national level, there could be some States you just want to regulate a whole lot more?

Mr. JONES. That absolutely I think would be the case.

Mr. BARROW. And the problem we have is not the fact that we have two regulators in any given one place.

Mr. JONES. Right.

Mr. BARROW. We only have 51 regulators as far as the country as a whole is concerned. You recognize the challenge and burden that is to industry.

Mr. JONES. That is right, and I think that that is the flipside of the—that is why I think it has been so hard for people to come together to figure out what is exact—what is that sweet spot there. It is untenable to try to sell a product in the United States, and you need to meet 51 or 57 different requirements. At the same time, you don't want to leave everybody unprotected because people here are not able to get their job done, or don't have the tools to get their job done. And trying to find that sweet spot, I think is very challenging.

Mr. BARROW. Thank you. With my—with that, my time is up.

Mr. SHIMKUS. Gentleman yields back his time.

And I—just a point. I think there are only like four States who really have the capability or are involved in this space, versus the other ones that aren't. And when we had ECOS testifying, many States had no capability to do this intensive evaluation. So I just throw that in.

Mr. Jones, a delightful testimony. I usually don't say that very often. Great job. I think you could see from the interest by members present that there is a desire to try to get this right, and find the sweet spot, and I hope we can continue moving forward. You are a great credit to the Agency, and we thank you for joining us. And we dismiss you and ask the final panel to come forward.

We would like to welcome the third panel here, and many of you have been sitting in the room for a couple of hours now, so we appreciate your diligence and we look forward to your testimony. I think the first two panels went real well, and we look forward to yours.

So I will just do the introductions as your opening statements are called for. It is great to welcome back Cal Dooley, former colleague, now President and CEO of the American Chemistry Council. Obviously, your full statement has been submitted for the record. You have 5 minutes.

STATEMENTS OF CAL DOOLEY, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN CHEMISTRY COUNCIL; ERNEST ROSENBERG, PRESIDENT AND CHIEF EXECUTIVE OFFICER, AMERICAN CLEANING INSTITUTE; RICHARD A. DENISON, SENIOR SCIENTIST, ENVIRONMENTAL DEFENSE FUND; DEAN C. GARFIELD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, INFORMATION TECHNOLOGY INDUSTRY COUNCIL; ANDY IGREJAS, DIRECTOR, SAFER CHEMICALS, HEALTHY FAMILIES; AND WENDY E. WAGNER, JOE A. WORSHAM CENTENNIAL PROFESSOR, UNIVERSITY OF TEXAS SCHOOL OF LAW

STATEMENT OF CAL DOOLEY

Mr. DOOLEY. Thank you, Chairman Shimkus, and Ranking Member Tonko, and all the members of the committee. I appreciate this opportunity to be testifying on behalf of the American Chemistry Council, our member companies, as well as 800,000 men and women who work every day in the business of chemistry.

ACC and our member companies are absolutely committed to the modernization and the reform of TSCA that will enhance the public confidence in the safety of our chemicals, and allow our industry and our customer base throughout the value chain to continue to be on the forefront of developing innovations that improve our everyday lives.

You know, some of you were in attendance at a hearing that this committee had in 2010 on a bill that was introduced to reform TSCA by Congressman Waxman. If you were here at that hearing, it was actually one that was fairly contentious, and Richard Denison and I were passionate defenders of our constituencies, but unfortunate, you know, that contentious dialog we had there was a reflection of what—the failure to find a common ground or a balanced approach to a comprehensive TSCA reform. It is unfortunate over the last few years, even on the Senate hearings where Mr. Denison, representing EDF, and I have testified, we were also very polarized and very contentious in some of our dialog. And that was a reflection of the failure for Republicans and Democrats to come together to find a balanced comprehensive reform to TSCA that could secure bipartisan support.

You know, that all changed just this last year when, thanks to the leadership of Senator Lautenberg and Senator Vitter, they brought together diverse constituencies to work out some of our differences, and develop not a perfect bill by either of our perspectives, or any of our perspectives, but develop a balanced approach that could provide for meaningful improvements to TSCA regulations. And it was really that balanced approach that was also groundbreaking in that we were able to develop the support of 25 members of the U.S. Senate, equally split, well, 12 to 13, between Republicans and Democrats. Again, unprecedented. And I really appreciate the work that this committee has done to try to find ways which we can build upon the progress that was achieved in the Senate, because our industry, and the value chain at large, has also increased their support in TSCA reform, because it is not only the chemical industry, it is the information technology industry, there is actually now an alliance of about 100 different associations representing everyone from the retail federation to toy manufacturers to automobile manufacturers, technology, semiconductors, that have all come together to support the CSIA, because they see it as a balanced and a meaningful reform of the existing TSCA legislation.

Also unprecedented is not only industry, but you also have organized labor that has joined in support of TSCA reform. You have the electrical workers and IBW, the North American Building Trades, the machinists, aerospace, transportation, and the ironworkers have also joined in support.

So the message here is is that, you know, something that is positive is happening here. We have also heard in some of the comments of Jim Jones as well as Administrator Gina Jackson that the CSIA really does set the foundation for meaningful progress to see reform of TSCA today. It is also, I think, important that when you look at the comments by former Administrator Christine Todd Whitman, and Charlie Auer who was manager of the TSCA Program under President Bush, as well as Steve Owens who was

President Obama's appointment that had jurisdiction over TSCA reform, that have also came and support and endorse CSIA. And they did so because they recognize that they address many of the problems that they had concerned with implementation of TSCA. It requires a systematic evaluation of all grandfathered chemicals for the first time. It prioritizes chemicals for EPA reviews so chemicals with the greatest need get the first and greatest attention. It gives EPA more efficient authority and ability to get the data that they need to make the determinations, and it requires EPA to make more information available to the public, a leading goal of environmental advocates and industry alike.

You know, we recognize at ACC that there are some members in the NGO community that would like to see some reforms and some modifications of the existing law, but when we look at the 5 issues that they surfaced early on, we think that those can be addressed in a meaningful and appropriate way that can build and improve upon CSIA, but does not, I guess, disrupt or create an imbalance in this coalition that could put us back into the gridlock that has been characterized in our ability, or our lack of ability, to achieve TSCA reform over the past better part of 37 years.

You know, I will be pleased to respond in detail to a lot of the questions you have, but my message here is, is that, you know, this bill isn't viewed by being perfect by industry, and I know Dr. Denison will say it is not viewed as perfect by the Environmental Defense Fund, but all of you that are serving in Congress today, just like I served for 14 years, know that there are very few perfect pieces of legislation from one constituent's interest. The only way we are going to see progress in enacting TSCA reform is it is going to take a balanced, comprehensive approach, and I hope that we use the CSIA as that foundation. I know that there are opportunities to make those modest and marginal reforms that will address some of those legitimate issues, but we have to be concerned of the delicate balance that we have in place here, and assure that we don't disrupt that.

[The prepared statement of Mr. Dooley follows:]

Testimony of

The Honorable Cal Dooley
President and CEO

American Chemistry Council
700 Second Street NE
Washington, DC 20002

Before the

United States House of Representatives
Subcommittee on Environment and the Economy of the
Committee on Energy and Commerce

"S. 1009 – The Chemical Safety Improvement Act"

November 13, 2013

Chairman Shimkus, Ranking member Tonko, thank you for the opportunity to testify on behalf of the American Chemistry Council, our member companies, both large and small, and the nearly 800,000 men and women who work every day in the business of chemistry. ACC and our members are committed to modernizing TSCA to enhance public confidence in the safety of chemicals and to allow our industry to continue to deliver the innovations that improve the quality of our everyday lives.

My last appearance before this committee to discuss TSCA in 2010 had left me with little hope that the common ground needed to make reform a reality could emerge.

But what a difference a few years can make.

The bipartisan Chemical Safety Improvement Act (CSIA), introduced by the late Senator Frank Lautenberg and Senator David Vitter, supported by equal numbers of Republican and Democrat co-sponsors, has kick-started a sincere and serious effort to reform chemical regulation. Senators Lautenberg and Vitter deserve enormous credit for their ability to secure concessions from all stakeholders in the development of this compromise legislation, and I commend this committee for advancing the important work they started last May.

Support for TSCA reform has grown dramatically. For many years, TSCA received little attention from anyone other than chemical manufacturers. But today, industries from electronics producers, big box retailers, auto makers, toy manufacturers and nearly 100 others, all understand that more effective chemical regulation is good for their customers, and therefore, good for them. They are urging passage of the CSIA.

Organized labor including the Electrical Workers, the Building Trades Unions, the Machinists and Aerospace Workers, the Transportation Division of SMART-Union, and Iron Workers have weighed in supporting the CSIA. They are joined by local chapters of various unions in Maryland, Montana, Missouri, New Mexico, New York, Pennsylvania and Virginia, each with the message that the CSIA is good for America's workers.

Mainstream environmental groups like the Environmental Defense Fund have acknowledged that the CSIA represents our very best chance for reform. Even EPA Administrator Gina McCarthy has said that we have a window of opportunity that we should not allow to close.

The CSIA has attracted support from such disparate quarters because this delicately crafted compromise will enhance public safety while preserving the ability of American manufacturers to develop new, life-changing innovations, compete in the global marketplace and create new opportunities in communities across the country. This much needed balance has eluded us in past reform proposals.

The CSIA will address numerous long-standing concerns about chemical regulation, including:

- Requiring a systematic evaluation of grandfathered chemicals for the first time;
- Prioritizing chemicals for EPA review so chemicals with the greatest need get the first and greatest attention;
- Giving EPA more efficient authority to demand further testing and additional data from chemical manufacturers;
- Requiring EPA to make more information available to the public, a leading goal of environmental advocates and industry alike.

Despite the significant improvements embedded in the current version of the bill, I understand that the NGO community has five primary issues they would like addressed: attention to sensitive subpopulations; preserving state authority to regulate chemicals; EPA's ability to restrict chemicals; data requirements; and deadlines.

We believe that these concerns are manageable and may be based on misperception or misunderstanding.

For example, the CSIA makes clear that sensitive subpopulations must be considered in the safety assessment process and any intended use that would expose these groups would again be weighed during the final safety determination.

The CSIA *preserves* the majority of state authorities and chemical laws, including California's Proposition 65, and will have no effect whatsoever on state water or pollution programs. But it also creates a more coherent, unified national approach to chemical regulation, which is desperately needed.

The bill will make it *easier* for EPA to take action to manage chemical risks.

Incentives for manufacturers to provide sufficient health and safety information are baked in to prioritization process.

And deadlines *will* exist, but they will be established by *EPA* based on the task at hand rather than arbitrarily prescribed in the legislation.

We believe that with a true commitment to reform on both sides, these issues can be addressed. But, it's important to realize that the CSIA is already the product of extensive negotiation and compromise. We support efforts to find common ground, and believe it is achievable, but any

effort to continually move the goal posts will undermine the trust that has been established thus far and could prevent progress for years to come.

We are hopeful that with continued leadership from this committee and from bipartisan leaders in the Senate we can seize this truly unique opportunity to pass legislation that is important to the lives of American families and the success of American manufacturers.

With that, I'd be happy to take questions.

Mr. SHIMKUS. Gentleman's time expired.

Chair now recognizes Mr. Ernie Rosenberg, President and CEO of the American Cleaning Institute.

STATEMENT OF ERNEST ROSENBERG

Mr. ROSENBERG. Thank you, Chairman Shimkus, Ranking Member Tonko, members of the subcommittee. My name is Ernie Rosenberg, thank you, and I am the President and CEO of the American Cleaning Institute.

Our member companies have facilities in the Congressional districts of two thirds of the subcommittee membership, and the—our members' products are in every home in the country.

Strengthening the Toxic Substances Control Act is a top priority for our member companies. That is why I am here today. A strengthened TSCA has the potential to promote consumer and environmental protection, while enabling innovation for new and improved products. That is why we support the Chemical Safety Improvement Act.

This legislation provides a strong roadmap for action in the 113th Congress. We commend the bipartisan efforts that led to the development of this measure, and especially the work of the late Senator Frank Lautenberg and Senator David Vitter. Twenty-five Senate Republicans and Democrats are cosponsors of what is truly bipartisan legislation.

A lack of confidence in TSCA has prompted States, local jurisdictions and businesses to restrict certain chemicals. These actions, unfortunately, create a regulatory and business climate that is driven by perceived safety concerns, not by sound science.

Allow me to highlight three important reasons for strengthening TSCA. First, a credible Federal program is crucial to having both a national market and improve public confidence in EPA's regulatory program. Second, TSCA must account for ongoing improvements in scientific methods and processes being developed by universities, the government and industry. This information must be considered by EPA when making safety assessments and determinations. Third, TSCA has fostered innovative chemical developments in the United States. We must ensure that this continues in the years ahead. Cleaning product manufacturers are leaders in the development of green chemistries that have led to significant energy savings, water savings and reductions in waste generation in the United States. The development of concentrated laundry and household cleaning products allows products that pack greater cleaning power in much smaller packaging to provide the benefits I have mentioned, and this represents just a few of the innovative, convenient and greener products that are available to consumers today. TSCA's new chemicals program encourages speed to market for such innovative products because of the rigorous and flexible way the law addresses this task. EPA relies on the strong interaction between government industry to make this happen, and has since the—since I was the manager of the program at the very beginning. The Chemical Safety Improvement Act preserves the efficiencies in the new chemicals review process, which are widely acknowledged to work well and are critical to innovation. To remain

innovative, we need strong protection for confidential business information.

A strengthened TSCA can and must be risk-based, and must be—must use the best science. EPA must be able to get the information it needs to make an informed chemical assessment and risk-management decisions. The Chemical Safety Improvement Act strengthens TSCA. It removes barriers to EPA data gathering and regulatory actions. I would call upon EPA to evaluate the safety of chemicals already in use, and enable the EPA to identify and act on chemicals that may pose significant safety concerns.

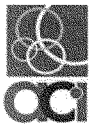
EPA's enhanced ability to obtain data would encourage industry to provide health and safety information to the Agency without regulatory delays, and with fewer demands on Agency resources.

CSIA also allows more data to make—be made available to the public. For the law to be credible, this is critical. It would also open up lines of communication between the States and EPA, and allow EPA to share information with them, including confidential business information, something TSCA does not currently allow. CSIA would allow EPA to meet its regulatory obligations, and restore confidence in the Agency's ability to do so.

For the law to become more credible, changes to TSCA must be practical, achievable and workable.

ACIA again thanks you for the opportunity to testify today, and I look forward to your questions.

[The prepared statement of Mr. Rosenberg follows:]



Summary of Testimony: ACI[1] President & CEO Ernest Rosenberg
S. 1009, the Chemical Safety Improvement Act (CSIA)
Subcommittee on Environment and the Economy
November 13, 2013

ACI supports the Chemical Safety Improvement Act (S. 1009), a bipartisan framework for strengthening TSCA. ACI companies have facilities in two-thirds of the districts of the Subcommittee membership.

ACI urges Congress and policymakers to ensure that updates to TSCA result in a credible and workable program for the EPA and industry, and allows EPA to meet its regulatory obligations without unduly delaying or burdening innovation. The U.S. chemical management system must be risk-based and use the best science so as not to waste or misdirect resources. Improvements in the law should reflect recent progress in science and technology and advance further innovations. A modernized TSCA has the potential to promote even greater innovation in the development of evermore sustainable cleaning products. CSIA accomplishes these goals.

The modernization of TSCA is important to the cleaning products industry in three areas ***because a*** -

1. Robust and credible federal program is crucial to the national uniformity that industry requires. Without this, our ability to be responsive to concerns that may be raised about chemicals in cleaning products — especially those concerns not based on reliable science — is significantly hampered.
2. Modernized TSCA is important to account for scientific developments and advances that allow important information developed by industry to be incorporated into chemical safety assessments and determinations.
3. Strengthen TSCA has the potential to promote the kind of innovation that our members consistently use in developing and creating more effective and sustainable cleaning products.

***Protection of Confidential Business Information (CBI)*:** TSCA must continue to provide robust, effective and predictable CBI protection. This will provide industry confidence that they will be able to reap the benefits of their expenditure of both time and resources in research and development leading to the creation of more sustainable products. Limits on the ability of industry to preserve CBI and prevent illegitimate use of intellectual property would discourage innovation and hinder the introduction of safer chemical alternatives.

***Speed to Market of Innovation*:** New products and greener chemistries get to U.S. consumers as fast as innovation allows because of the efficient method TSCA provides to accomplish this task. The TSCA premanufacture program is a better constructed process than any command and control regime which demands reams of data, irrespective of any health or safety concern. Hallmark features of the program that set the U.S. system apart from other regimes around the world include minimal delays, robust interactions between government and industry, and data flows all designed to meet key health and environmental goals.

***CSIA Strengthens TSCA*:** The CSIA directs EPA to systematically evaluate the safety of existing chemicals in use, and enables EPA to identify and act on chemicals that may pose safety concerns in their intended use. CSIA would allow more data on chemicals and Agency safety assessments to be made available to the public while respecting legitimate CBI; require rigor in CBI substantiation; and, will open up lines of state and federal government communication on issues of chemical safety. CSIA will preserve the efficiency of the current review process for new chemicals. CSIA would also provide needed uniformity on chemical management, and will encourage information data flows to better inform chemical assessment and risk management decisions.

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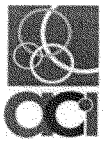
[1] ACI is the trade association representing the $30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. Our mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. More information can be found at www.cleaninginstitute.org



Testimony of

Ernest Rosenberg, President & CEO, American Cleaning Institute

S. 1009, the Chemical Safety Improvement Act (CSIA)

Subcommittee on Environment and the Economy

November 13, 2013

Introduction & Background

Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee on Environment and the Economy, I am Ernie Rosenberg, President and CEO of the American Cleaning Institute® (ACI)[1]. On behalf of the home of the U.S. cleaning products industry, I appreciate the opportunity to appear before the Subcommittee to provide testimony. ACI welcomes the bipartisan interest of the Subcommittee in the modernization of this important law. ACI companies have facilities in the congressional districts of two-thirds of the Subcommittee membership.

The American Cleaning Institute Supports the Modernization and Strengthening of our Nation's Premier Chemical Management Law

ACI and its members support the modernization and strengthening of TSCA. ACI has called for strengthening TSCA for several years before the recent Congressional efforts to amend the law.

[1] ACI is the trade association representing the $30 billion U.S. cleaning products market. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. Our mission is to support the sustainability of the cleaning products industry through research, education, outreach and science-based advocacy. More information can be found at www.cleaninginstitute.org

ACI is committed to efforts to enhance public confidence in the federal management of chemicals through the strengthening of TSCA. We recognize that consumers have an increasing awareness of chemicals used in everyday products.

ACI members are developers of innovative products which have improved performance and convenience and have delivered significant energy, water, and waste reducing technologies to consumers. A modernized TSCA has the potential to promote even greater innovation in the development of evermore sustainable cleaning products. These products provide essential benefits to consumers while protecting human health and the environment. The sustainability mission for ACI is to benefit society and improve quality of life through hygiene and cleanliness – and by driving sustainability improvements across our industry and throughout the supply chain. From cold water washing to efficiencies in cleaning product and packaging delivery, many of our members are building sustainability platforms across their businesses and throughout their supply chains. Chemical innovations help bring these sustainable products to our lives. With leadership from our member companies, ACI sustainability initiatives are demonstrating transparency by reporting aggregated environmental metrics data using sound science and outreach to show how cleaning products and ingredients enhance health and quality of life, and communicating ways in which consumers can use these products safely and responsibly.

Our industry supports S. 1009, the Chemical Safety Improvement Act (CSIA). We welcome the bipartisan development of this measure, and particularly the efforts of the late Senator Lautenberg (D-NJ) and Senator Vitter (R-LA), in crafting a compromise bill and obtaining bipartisan Senate co-sponsorship. ACI has been, and expects to continue to be, an active

participant in bipartisan engagements to advance the modernization of TSCA. The CSIA presents a valuable framework and roadmap for improvements to TSCA.

Our industry has been working with companies and trade associations up and down the value chain, among others, for some time on updating the law. Common ground has been established. Some of the most basic principles for updating TSCA include:

- The need to reflect the scientific advances made since the 1976 enactment of TSCA and to allow greater data sharing so that public health and environmental health interests are protected.
- Retention of the law's risk-based principles (which permit risk management decisions to be founded on a consideration of both hazard and exposure criteria), while enabling EPA to review and assess the safety of chemicals in a prioritized fashion.
- Encouraging innovation by ensuring speed to market for new products, growing jobs, and permitting our industry to compete in the global marketplace while protecting confidential business information.

The Modernization of TSCA is Key to Domestic and U.S. Global Chemical Leadership

The modernization of TSCA is important in three areas. First, a robust and credible federal program is crucial to the national uniformity that industry, particularly the consumer packaged products industry, needs. Public awareness of chemical substances and human and environmental exposure to them has changed in the nearly four decades since the law's enactment. An updated TSCA will contribute to improved public confidence in the chemicals used to manufacture consumer products and packaging. Second, a modernized TSCA is important to account for scientific developments and advances that allow important information developed by industry to be incorporated into chemical safety assessments and determinations. The law needs to be updated in order for the U.S. to continue to set the pace. Third, a

modernized TSCA has the potential to promote the kind of innovation that our members consistently use in developing and creating more effective and sustainable cleaning products.

TSCA is an important statute to ACI members because of the impact it has on American manufacturing and the freedom to formulate the products that the public wants and needs. For this reason, TSCA is particularly important to manufacturers who develop product and process innovations. TSCA's new chemicals program has made safety a design requirement in the development of chemical substances and formulated products. Put another way, the TSCA new chemicals program has had a deterrent effect on the introduction of any new chemical that creates a likelihood of harm to human health and the environment while still fostering innovation. Fundamental to this is how TSCA facilitates the introduction of groundbreaking innovative and sustainable chemistries and does so more effectively and efficiently than any other system in the world.

U.S. jurisdictions – not just states but localities as well – are taking mandatory steps to manage chemical substances through actions such as bans, restrictions, or phase-outs. Businesses are making decisions about the chemical substances they use to make products more conscientiously than ever. Chemical substitutions driven by safety, or concerns about safety, are increasingly being demanded. ACI suppliers and formulators are working in a business climate that is being driven to restrict the use of certain chemicals in consumer products by perceived safety concerns. However, such actions in this type of climate are not often driven by thorough scientific analysis. Without a credible federal program, our ability to be responsive to concerns that may be raised about chemicals in any kind of product, including cleaning products — especially those concerns not based on reliable science — is significantly hampered.

EPA needs to have access to, and take full advantage of, information and data necessary to reach credible science-based chemical management decisions, and to keep current with the rapid advances in the science of toxicity screening and risk assessment for chemicals. ACI recognizes that the Agency needs sufficient information to better inform chemical assessment and risk management decisions. A modernized TSCA should require EPA to systematically prioritize and assess existing chemicals. The current statute requires updating because there are considerable hurdles that EPA must meet before it can identify chemical risks and take effective action. CSIA addresses this.

Congress should provide EPA with adequate resources and clear authorities to meet deadlines to do the work under a revised TSCA program. It is crucial to stress that any changes to TSCA must be practical and achievable in order to maintain U.S. leadership in innovation. It is essential that any modernization of TSCA results in a successful program that is credible and workable for the Agency and industry, and allows EPA to meet its regulatory obligations without unduly delaying or burdening innovation.

A Robust U.S. Chemical Management Law Must Maintain and Enhance Competitiveness

There are key aspects of TSCA that allow U.S. industry to remain competitive in the global marketplace and help maintain and create U.S. jobs. TSCA maintains research and development flexibility, along with the confidentiality of new technological developments, during all phases critical to marketplace innovation. To this end, ACI remains watchful for any changes to TSCA that would create unnecessarily high hurdles for market entry of sustainable or otherwise innovative chemistries that our industry makes and uses. The U.S. chemical management system must be risk-based and use the best science so as not to waste or misdirect resources. Moreover,

improvements in the law should reflect recent progress in science and technology and advance further innovations.

Cleaning product manufacturers are leaders in greener chemistry innovations. These unique and breakthrough developments often stem from existing or newly developed proprietary "knowledge capital." To that end, the law must provide robust, effective, and predictable confidential business information protection. This is a priority for our industry and for the development of new chemistries that advance sustainability. Data confidentially provisions must protect proprietary information in the U.S. to encourage innovation and protect businesses from intellectual property losses. These concerns extend to any limits on the protection of chemical identity, and to any arbitrary time limits on CBI claims. Amendments should not alter the current Freedom of Information Act (FOIA) protection of trade secrets under which rules exist for commercial and financial information that is privileged and confidential under the law. Requirements that would limit or presumptively force the expiration of CBI protections, even if there continues to be a legitimate business purpose, would be problematic.

ACI accepts that a level of transparency is required to achieve the credibility we seek. The protection of CBI is not at odds with a modernized TSCA. ACI supports enhanced EPA access to chemical health and safety effects information. However, arbitrary limits on legitimate claims of confidential business information would inhibit the development of more sustainable chemistries and products. Such limitations may actually and ultimately conflict with the aim of the law to protect human health and safety and the environment by discouraging the development of new data, and by discouraging manufacturers from exploring these innovations in the U.S. market. In this regard, the continued protection of CBI (including the specific identities of chemicals when appropriate) remains important to our members. Consistent with similar

provisions in other laws, medical and health professionals should be permitted access to confidential chemical identities to diagnose or administer appropriate medical care, subject to appropriate confidentiality agreements. The sharing of CBI with other government authorities could be useful to EPA and industry, provided that safeguards are in place granting CBI protection equivalent to that under TSCA and FOIA. The robust protection of CBI provides industry confidence that they will be able to reap the benefits of their expenditure of both time and resources in research and development leading to the creation of more sustainable products.

New products and greener chemistries get to U.S. consumers as fast as innovation allows because of the efficient method TSCA provides to accomplish this task. TSCA Section 5 gives EPA the authority to evaluate and regulate new chemical substances for use in the U.S. marketplace. In general, EPA accomplishes this through the receipt and expedient review of premanufacture notices (PMNs). The law allows EPA to review and take any necessary action even before there is any commercial production of the chemical substance. Only after the review period has expired and EPA has elected to take no action on the basis of health and safety concerns can commercial production commence. The individual chemical substance is then listed on an EPA inventory; but when it is appropriate, may be subject to future review. EPA accomplishes much of this work using information already in its possession, or from information and data submitted by manufacturers and processors, and by relying on constantly evolving assessment tools as an alternative to additional animal testing. While TSCA grants EPA control authorities, it has been repeatedly demonstrated that the Agency can also obtain additional information from the chemical manufacturer, or take more time for review. Such requests lead to the submission of new information or the withdrawal of the premanufacture notice.

The TSCA premanufacture program is a better constructed process than any command and control regime which demands reams of data irrespective of any health or safety concern. Moreover, the law allows EPA to interact and engage with chemical substance manufacturers faster and more flexibly than any other global regulatory counterpart. This is a fundamental reason why TSCA Section 5 has worked so well — and why the U.S. is where most chemical innovations are introduced. These important features of minimal delays, robust interactions between government and industry, and data flows to accomplish key health and environmental goals are paramount features that set the U.S. apart from other regimes around the world.

The Chemical Safety Improvement Act (CSIA) S. 1009 Strengthens TSCA

The CSIA would for the first time direct EPA to systematically evaluate the safety of existing chemicals in use. S. 1009 would also help the Agency take steps to clean-up its chemical inventory nomenclature system. It would also enable EPA to identify and act on chemicals that may pose safety concerns in their intended use. CSIA artfully and thoughtfully refocuses the TSCA safety standard on risks to human health and the environment, but would remove key obstacles to the Agency's use of its authorities. CSIA also seeks to strengthen the credibility of EPA's program and enable uniformity on chemical management which is so urgently needed.

Data collection by rule under existing TSCA authority is complicated and cumbersome. EPA has been very successful in obtaining new data from industry without resorting to rulemaking. The CSIA would provide a pathway for new testing agreements building on these successes. For those cases where EPA must require the submission of health and safety information, the CSIA would enable the Agency to more efficiently gather data with revised tools. The CSIA, unlike the law today, would allow EPA to more efficiently and expeditiously gather data when needed for the Agency to determine whether a chemical is safe for its intended use. This may include

additional testing and obtaining information from processors. EPA would be required to assess and affirmatively determine the safety of existing high priority chemicals under CSIA, which would create a persuasive environment for industry to voluntarily develop or bring forward a variety of new data to ensure EPA assessments are well informed. CSIA would create a coherent program to ensure EPA has the tools for making chemical assessments that are well informed by encouraging the Agency to first use existing data. This is analogous to the structure of Canada's effective law.

CSIA would significantly improve EPA authority to identify and act on chemicals that pose safety concerns. One of the biggest problems EPA faces in administering the current TSCA is the Agency's inability to achieve timely risk reductions under Section 6 when faced with the need to reduce or eliminate exposures to a specific chemical through a cumbersome rulemaking process. While Section 6 has good processes in theory, it has been shown to be next to impossible for the Agency to successfully implement in practice. CSIA would eliminate excessive impediments by streamlining the Section 6 process.

Finally, with regard to the two critical aspects important to the cleaning products industry addressed above, the CSIA would allow more data on chemicals and EPA's safety assessments to be made available to the public while respecting legitimate confidential business information (CBI). Limits on the ability of industry to preserve CBI and prevent the illegitimate use of intellectual property would discourage innovation and hinder the introduction of safer chemical alternatives. The CSIA recognizes the need to protect legitimate CBI, while requiring rigor in substantiation. The CSIA opens up lines of state and federal government communication on issues of chemical safety. The CSIA would do this while preserving the efficiency of the current

review process for new chemicals. This is critical to facilitating innovation in the U.S., and for bringing sustainable chemistries to market and allowing substitutions where warranted.

* * *

ACI is committed to remaining an engaged stakeholder to develop a constructive bipartisan, bicameral dialogue to update and strengthen TSCA. A credible federal chemical management program is important to promoting the safe use of chemicals; enhancing public confidence in the chemical management system; protecting American jobs; and, maintaining U.S. global leadership in chemical innovation. ACI appreciates the opportunity to engage as a direct participant with you on the most critical issues related to updating such an important law.

Mr. SHIMKUS. Thank you, Mr. Rosenberg.

Now I would like to recognize Dr. Richard Denison, Senior Scientist from the Environmental Defense Fund.

STATEMENT OF RICHARD A. DENISON

Mr. DENISON. Thank you, Chairman Shimkus, Ranking Member Tonko, and other members of the committee for your interest in this issue, and for the opportunity to share EDF's perspective on this bipartisan legislation, the Chemical Safety Improvement Act.

I have four key points I would like to make today.

First, we have a major political opening to address an urgent health concern, and to fix a law that everyone believes needs reform. Second, the bill before us has many of the elements needed for effective reform, and a concern for moving reform forward. Third, the bill also has serious problems that must be remedied. And fourth, those problems, while serious, are fixable.

The need for reform is more urgent than ever, with science increasingly linking exposures to certain chemicals to serious health effects.

My organization has been working to reform TSCA for more than 20 years, and I personally for well over a decade. The law simply does not work. It is not protecting the health of Americans, it doesn't provide the information companies need to make sound decisions, and it doesn't give consumers and the market the confidence that companies need to run their businesses.

In May of this year, we saw a breakthrough with the introduction of CSIA. The bill is both a promising start and far from perfect. It contains many elements of TSCA reform that need significant changes to actually deliver those reforms. I am convinced the problems can be addressed while retaining the bipartisan support needed to pass legislation.

Let me note several ways in which CSIA addresses major flaws in current law. For the first time safety reviews would be required for all chemical—in order to be made and sold. Also for the first time—gain access to confidential business information.

CSIA would address the two main reasons the TSCA safety standard has failed. It would generally replace the current cost benefit standard with a requirement for a health-only standard, and it strikes the least burdensome requirement for TSCA regulations that has, as Mr. Jones said, become a recipe for paralysis by analysis.

CSIA would also fix TSCA provisions that thwart EPA's ability to get new data on a chemical. It could issue test orders and avoid a regulatory process that takes many years. And it strikes the catch 22 under TSCA that requires the EPA first show evidence of risk in order to require testing. But the bill would also erect some major barriers to EPA effectively and efficiently using these new tools. The safety standard does not ensure protection of vulnerable populations, including pregnant women, infants, workers who may be more exposed or more susceptible to the effects. The bill would not ensure that all information claimed confidential actually warrants trade secret protections. It would weaken current TSCA by barring the testing of new chemicals, or ones lacking enough data to screen their safety. This means EPA would either have to give

a pass to data poor chemicals that may post a risk, or waste time scrutinizing chemicals that more data would show pose little risk. And the bill lacks deadlines and has so many procedural requirements that just getting the system up and running would take years.

My testimony includes an analysis I have done that is quite optimistic in terms of time frames that shows that more than 7 years would be required to get to the first safety determination for a chemical.

Finally, the bill's sweeping preemption of State authority needs to be significantly narrowed so that, for example, States can continue to act until and unless EPA takes final action on a chemical, and can, with good cause, obtain waivers that allow them to go further than a State than EPA—control of chemical risks.

Mr. Chairman, let me end on a positive note. The bipartisan bill offers major political opportunity and conserves the basis for talks to move reform forward, and while its deficiencies are serious, as I mentioned before, I believe they are all fixable. I am encouraged that the informal negotiations on the bill that have been occurring in the Senate already appear to be moving in the right direction, but there is more work to be done. I urge the subcommittee to build on the foundation laid by S. 1009 to pass meaningful TSCA reform legislation in this Congress. The health of—and I thank you for your time today.

[The prepared statement of Mr. Denison follows:]

WRITTEN STATEMENT OF

RICHARD A. DENISON, Ph.D.
SENIOR SCIENTIST
ENVIRONMENTAL DEFENSE FUND

BEFORE

THE U.S HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE
SUBCOMMITTEE ON ENVIRONMENT AND THE ECONOMY

AT A HEARING ON

S. 1009, THE CHEMICAL SAFETY IMPROVEMENT ACT OF 2013

13 NOVEMBER 2013

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ONE-PAGE SUMMARY

In May of this year, the bipartisan Chemical Safety Improvement Act (CSIA) was introduced, opening the first viable path toward actually passing TSCA reform legislation. CSIA contains many elements of effective reform – but needs significant changes if it is actually to deliver the promised reforms.

Some of the ways in which CSIA addresses major flaws in the current law include:

- CSIA mandates safety reviews of all chemicals already in commerce.
- CSIA tackles the key problems in TSCA's "unreasonable risk" standard, by clarifying that the standard is to be applied based solely on health and environmental risk, and striking the "least burdensome" requirement that has paralyzed EPA's ability to act.
- CSIA requires a new chemical to be found likely to meet the safety standard before market entry.
- CSIA increases EPA's ability to require testing, by allowing it to issue orders and not requiring EPA to make risk findings to order testing.
- CSIA grants State and local governments and medical personnel access to confidential business information (CBI), subject to confidentiality agreements.

Unfortunately, the bill as drafted also would erect major obstacles that would impede EPA's ability to effectively and efficiently utilize these tools. And it would unduly limit the authority of states to act to address chemical risks, often long before EPA has acted to address those risks.

Among the major concerns that need to be addressed are the following:

- The safety standard must ensure protection of vulnerable populations and require that the multiple sources of exposure to chemicals be taken into account.
- EPA's authority to require testing when reviewing new chemicals and prioritizing data-poor chemicals needs to be restored.
- The bill's sweeping pre-emption of state authority needs to be significantly narrowed.
- The bill's lack of deadlines and its imposition of numerous overlapping procedural requirements, which would delay even the first safety decisions for many years, must be fixed.
- The bill's undue limits on EPA's ability to ensure that information submitted and claimed as confidential actually warrants protection from disclosure must be remedied.

I am convinced that these problems, while serious, are fixable and can be addressed in a manner that ensures protection of public health while retaining bipartisan support critical to passage of the legislation. Congress must seize this opportunity to address an urgent health concern and overhaul an ineffective and obsolete law that everyone agrees needs reform. The health of all Americans hangs in the balance.

FULL STATEMENT

My organization has been working to reform the Toxic Substances Control Act (TSCA) for nearly 20 years and I have personally been engaged in this effort for well over a decade. We have made this investment because we are convinced that this outmoded law is not protecting American families, workers and communities from toxic chemical exposures.

The need for reform is urgent, even more so than when we began this work. Emerging science increasingly links certain chemical exposures to the rising incidence of serious chronic health problems such as infertility, diabetes, childhood cancers and even learning disabilities. So in recent years we have redoubled our efforts to reform TSCA, the core provisions of which have not been touched in nearly 40 years. Today, there is almost universal agreement that the current law simply does not work: It is not protecting American families, workers and communities from toxic chemicals; it is not providing the market with the information needed to inform decisions and drive innovation toward safer chemicals; and it is not providing the consumer confidence and market predictability that companies need to run their businesses.

In May of this year, we saw a breakthrough: For the first time, bipartisan reform legislation was introduced in the Senate, and the bill now enjoys co-sponsorship by one-quarter of the Senate, 12 Democrats and 13 Republicans. EDF welcomed the introduction of the Chemical Safety Improvement Act (CSIA) because it offers the first viable path toward actually passing reform legislation. In addition, the bill as introduced contains many of the elements of *effective* reform – although, as I will explain, as drafted it needs significant changes if it is to actually deliver the promised reforms.

EDF and many others have identified a number of serious concerns with CSIA that must be addressed, a few of which I'll discuss in a moment. But I am convinced that the problems are fixable and can be addressed in a manner that ensures protection of public health while retaining bipartisan support critical to passage of the legislation. Many, if not most, of the improvements we seek will benefit *all* parties by creating an effective and efficient system that protects public health and restores market and consumer confidence in the chemical and related industries and their products. I've attached to my testimony a side-by-side comparison of TSCA and CSIA, highlighting both strengths and weaknesses of the bill (**Attachment 1**).

Let me now highlight some of the ways in which CSIA addresses major flaws in the current law.

- **CSIA mandates safety reviews of all chemicals already in commerce:** When TSCA passed in 1976, it grandfathered in some 62,000 chemicals already in commerce – which still account for the bulk of chemicals in active use today – and gave EPA no mandate to review them for safety. As a corollary, it falsely equated the lack of any safety data on the great majority of those chemicals with a lack of risk.

  CSIA for the first time would require EPA to review the safety of all chemicals in active commerce. And it makes a lack of safety data a basis for designating a chemical high-priority, which triggers EPA's authority to require testing and a mandate to conduct a formal safety assessment and safety determination for the chemical.

- **CSIA tackles the key problems in TSCA's "unreasonable risk" standard**: TSCA's "unreasonable risk" cost-benefit standard is widely regarded to have failed for two main

reasons. First, it blurs together what should be two distinct decisions: a science-based decision as to *whether* a chemical poses a significant risk; and a risk management decision as to *how* to address such risks where they are found. Second, it forces EPA to engage in paralysis-by-analysis by requiring it to prove that any action it proposes to take is the "least burdensome" of all possible options for each and every use of a chemical.

CSIA tackles both problems: It clarifies that the "unreasonable risk" standard is to be applied "based solely on considerations of risk to human health and the environment;" except in the case of complete bans or phase-outs, consideration of costs and benefits is relegated to a separate risk management stage. And it strikes the paralyzing "least burdensome" provision.

- **CSIA requires that a new chemical be found likely to meet the safety standard before market entry:** Under TSCA, new chemicals undergo a cursory pre-manufacture review, and no affirmative safety decision is required before they can enter the market. And in the review, the burden is on EPA to find a concern – hard to do when safety data are not required – in order to halt, slow or limit market entry.

CSIA for the first time would require EPA to make an affirmative finding of likely safety as a condition for the manufacture of a new chemical to commence. And while EPA still could not directly require safety testing of new chemicals, it could suspend its review pending submission of needed data, or impose conditions needed to provide the requisite assurance of likely safety in the absence of such data.

- **CSIA allows EPA to require testing by issuing orders:** Under TSCA, EPA must promulgate a regulation in order to require a company to conduct safety testing of a chemical it makes or uses. Moreover, to require testing, EPA has to show potential risk or high exposure – a *Catch-22*, given that testing would typically be the way EPA would get the data needed to make such findings! This process is resource-intensive and typically takes many years.

  CSIA would authorize EPA to issue orders to require testing. Using orders avoids the onerous rulemaking process and subsequent court challenges. While EPA would have to justify why it is using an order rather than a rule or consent agreement, it would not need to make risk findings to order testing of a chemical.

- **CSIA grants State and local governments and medical personnel access to confidential business information (CBI), subject to confidentiality agreements:** Under TSCA, EPA is forbidden from sharing CBI with other levels of government, denying them access to information vital to their ability to assure the health and welfare of their citizens. And even in emergency situations, TSCA denies doctors, nurses, even staff in poison control centers, access to information – such as the confidential identity of a chemical to which a child or worker has been exposed – that could literally save lives.

  CSIA would for the first time grant access to such information to those outside the Federal government who need it most.

  That's the good news.

Unfortunately, the bill as drafted also would erect major obstacles that would impede EPA's ability to effectively and efficiently utilize these tools. And it would unduly limit the

authority of states to act to address chemical risks, often long before EPA has acted to address those risks.

Among the major concerns that need to be addressed as the bill moves through the legislative process are the following:

- **The safety standard must ensure protection of vulnerable populations and require that the multiple sources of exposure to chemicals be taken into account.** One thing we have learned since TSCA first passed in 1976 is that certain individuals and populations are either more heavily exposed to chemicals or more susceptible to their effects than the population as a whole. These include the developing fetus and infants, as well as workers or those with pre-existing medical conditions. And they include "hotspot" communities that have disproportionately high exposure, often because they are exposed to chemicals from multiple sources.
- **EPA's authority to require testing when reviewing new chemicals and prioritizing data-poor chemicals needs to be restored.** As noted earlier, CSIA would reduce the procedural and evidentiary burdens on EPA to require testing. However, it would severely limit the purposes for which testing could be required: Testing could only be required to inform safety assessments and determinations for existing chemicals, and EPA is explicitly barred from requiring testing of new chemicals and to inform prioritization of existing chemicals. This is a major step backward from current TSCA. The arbitrary restriction on testing in CSIA would lead to one of two outcomes that would be good for no one: either EPA would be forced to allow chemicals for which insufficient data exist to assess their safety to enter or

remain on the market; or it would have to deny market access to or waste resources assessing chemicals that more data would show pose little or no risk.

- **The bill's sweeping pre-emption of state authority needs to be significantly narrowed.** Foremost among the concerns about the bill as drafted is that by EPA merely designating a chemical as high- or low-priority, all States would be precluded from imposing a new requirement on the chemical. For a high-priority chemical, this pre-emption of State authority would happen long before, likely many years before, EPA took any action to address risks posed by that chemical. And for a low-priority chemical, States that disagree with EPA's decision would have no recourse because even though the low-priority designation would effectively be a final agency action, it would not be subject to judicial challenge. That's not only bad policy, it's bad for the practice of government.

  Under the bill as drafted, pre-emption of pre-existing state requirements is triggered merely by EPA's issuance of a safety determination. For a chemical EPA finds does not meet the safety standard, State requirements would be voided well before EPA takes final action to address the risks of the chemical.

  Long-standing authorities of states to enact requirements identical to those of Federal agencies for purposes of co-enforcement would also be eliminated, as would state requirements imposed for entirely different purposes such as to reduce emissions of greenhouse gases.

- **The bill's lack of deadlines and its imposition of numerous overlapping procedural requirements, which would delay even the first safety decisions for many years, must be fixed.** One area of agreement across all stakeholders is the desire for an efficient system

that gets up and running quickly, transitions smoothly from the current system, and makes timely decisions on the large number of chemicals in active commerce. As drafted, the bill would frustrate that shared objective by requiring EPA to take years just to establish the new system, and years more to make decisions and take action on specific chemicals. And it would all but invite legal challenges by parties unhappy with one or another aspect.

I have done a detailed analysis of the bill's procedural requirements, which I've attached to my testimony (**Attachment 2**). It shows that even by a very conservative estimate, the first list of prioritized chemicals would take more than three years to develop, and the first safety determination on a chemical not made until more than seven years after enactment, with any needed risk management actions requiring even longer to implement.

Solutions to these problems are, however, evident: Among them are adding aggressive but realistic deadlines; ensuring EPA can incorporate and build on the work it has done to date as it transitions to the new system the bill would establish; and streamlining the bill's "red tape" to eliminate redundant requirements and procedures.

- **The bill's undue limits on EPA's ability to ensure that information submitted and claimed as confidential actually warrants protection from disclosure must be remedied.** For example, the bill places a blanket restriction on EPA's authority – which it has under current TSCA – to examine and require documentation of past confidentiality claims – even when it has reason to believe the information does not or no longer constitutes a trade secret. Given the widespread overuse of CBI allowances over the history of TSCA – a fact acknowledged even by industry witnesses appearing before this Subcommittee earlier this

year – this restriction is unwarranted and could even preclude EPA from complying with requests its receives under the Freedom of Information Act (FOIA).

Let me end by returning to what I believe is the good news here: First, we have a major political opening to address an urgent health concern and overhaul an ineffective and obsolete law that everyone agrees needs reform. Second, we have a bill that has many of the elements needed for effective reform and can serve as a basis for negotiations. Third, while its deficiencies are serious, they are fixable: many of the changes needed I believe will benefit all parties, and the others, while tougher, can be solved if we can muster the political will and negotiate in good faith to balance competing objectives. I am encouraged that the informal negotiations on the bill that have occurred to date appear already to be moving it in the right direction.

I urge this Subcommittee and all stakeholders to build on the foundation laid by a bipartisan group of Senators earlier this year and work to pass meaningful TSCA reform legislation in this Congress.

The task will not be an easy one, but we simply can't afford to waste this opportunity. If done right, the bill could pave the way to an effective and efficient system that fully protects public health, restores lost confidence in the safety of chemicals and chemical products, and provides incentives and the information needed for the market to avoid dangerous chemicals and innovate safer and greener ones.

The health of all Americans hangs in the balance.

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ATTACHMENT 1

The Chemical Safety Improvement Act of 2013 (S. 1009): How it seeks to address key flaws of TSCA, along with key tradeoffs and concerns

Prepared by

Richard A Denison, Ph.D.
Senior Scientist
Environmental Defense Fund
November 2013

The Chemical Safety Improvement Act of 2013 (CSIA, S. 1009) would amend the core provisions of the Toxic Substances Control Act (TSCA) for the first time since TSCA's passage in 1976. Over the years, key flaws in these core provisions have been identified by many observers. **Table 1** below shows how these key flaws in each core area of current TSCA would be addressed by the new legislation. It also identifies some of the main trade-offs and remaining concerns raised by these provisions of the legislation. **Boldfaced entries** are those I consider to be most central to addressing the question of how and to what extent the new legislation fixes the key flaws of TSCA.

The bill would significantly expand TSCA's currently limited pre-emption of state authority, which has largely been moot due to how few actions EPA has undertaken. **Table 2** below presents the key pre-emption provisions of current TSCA and CSIA are presented along with key issues and concerns raised by the bill's expanded provisions.

This analysis does ***not*** address other critically important aspects of the debate over TSCA reform, including the absence from the new legislation of provisions – which I and many others support – that would extend the scope of TSCA beyond its core provisions, including those relating to: (1) "hot spots" – areas with disproportionately high chemical exposures; (2) expedited exposure reduction for chemicals of very high concern, such as PBTs; and (3) green chemistry and alternatives assessment.

TABLE 1	*Key flaws in TSCA*	*Key changes in CSIA*	*Trade-offs/remaining or new concerns*
Safety standard/ determination ***(Section 6)***	• **Standard requires cost-benefit analysis** • **Imposes "least burdensome" requirement on any regulation** • No definition or specific criteria to identify chemicals of concern	• **Standard is applied based on health/ environment impacts only** • **Strikes "least burdensome" requirement** • Requires EPA to consider exposures of vulnerable populations • Requires EPA to consider multiple exposures to a chemical • Requires EPA to use "best available science"	• Bans still must be based on cost-benefit • No explicit inclusion in standard of protection of vulnerable populations or need to assess aggregate exposure • "Best available science" does not reference NAS recommendations
Existing chemicals ***(Section 6)***	• **No mandate to review existing chemicals for safety** • **Lack of data is presumed to indicate lack of risk** • No criteria for triggering review of an existing chemical	• **Requires a safety review of all chemicals in active commerce** • **Lack of data is basis for high-priority designation** • High hazard or exposure sufficient for high-priority designation • Requires safety determinations for all high-priority chemicals • Requires risk management to be imposed on chemicals found not to meet the safety standard	• Initial review (prioritization) is based only on existing data, and lack of data does not assure high-priority ranking • Pace of review is unspecified, with virtually no deadlines for EPA actions • Prioritization decisions not subject to court challenge (cuts both ways) and can trigger pre-emption of state authority • Overly prescriptive and redundant frameworks and criteria must be developed and followed
New chemicals ***(Section 5)***	• **No affirmative safety decision is required before market entry** • **Burden is on EPA to find concern even when safety data are lacking** • Decisions are largely a "black box" because consent orders need not be made public	• **An affirmative decision of "likely safety" is required for market entry** • Prohibitions or restrictions can be imposed by order • All new chemical notices and orders and submitted data must be made public (subject to CBI provisions)	• EPA cannot require testing of new chemicals (but can suspend review or impose conditions, as in status quo) • No means provided to ensure compliance for chemicals "likely" to meet safety standard (unless EPA issues a Significant New Use Rule, or SNUR)
Testing ***(Section 4)***	• **EPA must promulgate a regulation to require testing** • **EPA has to show potential risk or high exposure to require testing, a Catch-22** • Testing done by consent orders is non-transparent, not always made public	• **EPA can use orders to require testing (must justify why it is using an order rather than a rule or consent agreement)** • **Testing orders avoid lengthy rulemaking and court challenges** • **EPA does not need to make risk findings to require testing** • Testing agreements and orders and all test data must be made public (subject to CBI provisions)	• Testing can only be required for use in safety assessments or determinations, hence limited to chemicals in commerce deemed high-priority • No minimum information sets are required; all testing is on the basis of EPA demonstrating specific need • An overly prescriptive tiered testing framework must be followed

TABLE 1	*Key flaws in TSCA*	*Key changes in CSIA*	*Trade-offs/remaining or new concerns*
Confidential business information ***(Section 14)***	• **Companies can claim any information they submit to be CBI** • **Substantiation of CBI claims is typically not required** • **EPA reviews very few CBI claims and must challenge them case-by-case** • **EPA cannot share CBI with state and local governments** • Health and medical professionals cannot be given access to CBI • CBI claims do not expire	• Information never eligible (as well as eligible) for CBI is delineated • **All other CBI claims must be substantiated at the time asserted** • Resubstantiation can be required for any CBI claim upon designation of a chemical as high-priority • **EPA must review CBI claims (all or representative subset)** • **States and localities have access to CBI, subject to confidentiality agreements** • Health professionals can access CBI under confidentiality agreements • For chemical identity CBI claims: ▪ Redocumentation can be required at any time ▪ Ready capability for reverse engineering disallows such claim ▪ A time period must be specified for each such CBI claim and found by EPA to be reasonable	• Only health and safety data on existing – not new – chemicals is precluded from being claimed CBI • Notifications to submitters prior to release of CBI are generally required • A new appeals process is provided under which claimants can challenge EPA's intention to release CBI • Except as noted for chemical identity and high-priority chemical CBI claims, EPA cannot require documentation or redocumentation of a CBI claim made prior to the date of enactment
Chemical information reporting ***(Section 8)***	• The full range and identity of chemicals in active commerce, and their producers and processors, is not known • **Information on use of chemicals is collected only from chemical manufacturers with limited knowledge of downstream use**	• Companies must notify EPA of all chemicals on the TSCA Inventory they are producing or processing (used to "reset" the Inventory) • Chemicals not notified as active are placed on an inactive list; a company must notify EPA before making them • **Processor reporting is required for the first time for all chemicals in active commerce**	• Chemicals on the confidential portion of the TSCA Inventory can remain so if reasserted (though EPA can require (re)substantiation – see above) • The scope of manufacturer and processor reporting programs is left to EPA to develop through rulemaking

TABLE 2	TSCA	CSIA	Issues/concerns
Pre-emption ***(Section 18)***	• States can't require testing of a chemical "for purposes similar to those" for which EPA requires testing • If EPA regulates a chemical by rule, States can only: (a) have the identical requirement or (b) regulate it under a different Federal law or (c) entirely prohibit the chemical in the State • Only final rules or orders have a pre-emptive effect • Waivers available for State requirements that are more protective and don't unduly burden interstate commerce	• States can't require testing "reasonably likely to produce the same data" as EPA requires, or require notification of uses of a chemical for which EPA requires the same notification • States can't establish or continue to enforce a requirement that restricts a chemical once EPA has completed a safety determination on the chemical • States can't impose a <u>new</u> restriction on a chemical once EPA has: (a) designated it low-priority, or (b) for high-priority chemicals, upon publication of EPA's schedule for conducting a safety assessment and determination • Waivers available if State cannot wait for EPA to act or EPA finds its actions are being unreasonably delayed	• States need to be able to enact requirements identical to EPA's to allow for co-enforcement • "Restriction" can be read broadly to apply to warning labels, etc. (e.g., CA Prop 65) • The safety determination doesn't regulate a chemical found not to meet the safety standard; the trigger for any preemption should be the final risk management rule required for such chemicals • Low-priority designations can't be challenged in court as final EPA actions • The trigger for any preemption should only be (a) a determination that a chemical meets the safety standard or (b) the risk management rule required for chemicals found not to meet the standard • States must also show "compelling local" conditions or interests and sufficient scientific basis to obtain waivers

Attachment 2

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Conservative timeline for implementation of the Chemical Safety Improvement Act (S. 1009)

Date of enactment to first prioritized chemicals = 39 months or 3.25 years
Date of enactment to first final safety determination = 86 months or 7.17 years
Date of enactment to first final rule imposing restrictions = 104 months or 8.67 years

Process step or activity	**Minimum time required** (Conservatively assumes: (1) no additional data needed; (2) process timelines overlap or run concurrently wherever plausible; and (3) rules can be finalized in 18 months)	Minimum cumulative time (months)	Bill section
1. Promulgate reporting rule, guidance	18 months (may be done within timeframe of #4)		8(a)(4), (5)
2. Develop candidate list of active chemicals	6 months (may be done within timeframe of #4)		8(b)(4)(A)
3. Issue guidance on active chemical reporting	6 months (may be done within timeframe of #4)		8(b)(4)(B)
4. Promulgate rule requiring reporting of active chemicals	18 months	18	8(b)(4)(C)
5. Propose designations of each chemical as active/inactive	6 months	24	8(b)(5)-(7)
6. Provide an opportunity to comment/claim CBI	3 months	27	8(b)(8)
7. Modify active/inactive lists based on comments	3 months	30	8(b)(8)
8. Develop chemical assessment framework	12 months (concurrent with above activities?)		4(a)(1)
9. Develop policies and procedures for the framework	12 months (concurrent with #8?)		4(a)(2)
10. Develop data quality criteria	6 months (concurrent with #8?)		4(b)(1)
11. Develop structured evaluative framework	6 months (concurrent with #8?)		4(b)(5)
12. Develop prioritization screening process	12 months (concurrent with #8?)		4(e)(1), (2)
13. Propose prioritization criteria	3 months (concurrent with #12?)		4(e)(2)(A), (C)
14. Take public comment on the process and criteria	3 months (concurrent with #12?)		4(e)(2)(A)
15. Propose initial list, prioritization decisions for comment	3 months (concurrent with #12?)		4(e)(2)(B)
16. Request data submission on the initial chemicals	3 months	33	4(e)(1)(F)(ii)
17. Finalize priority designations for initial list	6 months	***39***	4(e)(3)(B)
18. Take public comment on subsequent high/low decisions	3 months (not included in initial timeline)		4(e)(3)(G)
19. Publish subsequent lists of high/low priority chemicals	3 months (not included in initial timeline)		4(e)(3)(J)
20. Promulgate procedural rules for safety assessments	18 months (partially concurrent with #8?)	45	6(b)(2)
21. Develop safety assessment methodology	18 months (partially concurrent with #8?)		6(b)(4)
22. Take public comment on and peer review methodology	12 months	57	6(b)(4)(A)(ii)
23. Seek input on first high-priority chemicals to be assessed	3 months (concurrent with #22?)		6(b)(2)(B)(i)(III)
24. Draft safety assessments on first high-priority chemicals	12 months	69	6(b)(1)
25. Take public comment on draft safety assessments	6 months	75	6(b)(2)(B)(i)(IV)(bb)
26. Publish final safety assessments on first chemicals	6 months	81	6(b)(2)(B)(i)(IV)(cc)
27. Propose safety determinations on assessed chemicals	1 month	82	6(c)(1)
28. Take public comment on draft safety determinations	2 months	84	6(c)(6)
29. Publish final safety determinations on first chemicals	2 months	***86***	6(c)(7)
30. Promulgate rules for chemicals not meeting standard	18 months	***104***	6(c)(9)

Mr. SHIMKUS. Thank you, Dr. Denison.

Now I would like to recognize Mr. Dean Garfield, President and CEO of the Information Technology Industry Council.

Sir, welcome.

STATEMENT OF DEAN C. GARFIELD

Mr. GARFIELD. Thank you, Mr.—Chairman Shimkus, Ranking Member Tonko, members of the committee.

On behalf of the 54 of the most dynamic and innovative companies in the world, as well as the nearly 6 million people who work in the tech sector, we thank you for hosting this hearing and asking us to testify.

We have submitted our testimony for the record, so rather than repeat it, I will highlight three elements of that testimony.

First, we strongly support this bipartisan and bicameral effort to reform TSCA. We think it is a unique opportunity to advance our human health and environmental shared interests. The tech sector takes very seriously its role as corporate and environmental stewards, whether it is in product design where we are driving down the energy usage of our products, or in sourcing where we are developing and promulgating responsible sourcing, paradigms and programs, or in our recycling and reuse programs that we have all across the world. We view these issues as first priorities and intend to stay engaged. And so thank you for your efforts.

Second, we think this regulatory reform creates an opportunity to develop regulatory processes that are timely, transport and based on sound science. In that regard, we will be placing particular emphasis and paying a lot of attention to how you deal with the issue of chemicals and articles. In particular, we think it is very important for Congress to give guidance to the EPA in that area, but at the same time, we don't think it should be done in an import/export control fashion, and, in fact, we think the current process whereby the EPA has a case-by-case analysis is one that is appropriate and should be continued.

Finally, we strongly agree with Chairman Shimkus' opening statement that TSCA reform can and should be an opportunity to enhance rather than inhibit innovation. With that in mind, we think it is important for three things to occur. One, as the previous witness, Mr. Jones, pointed out, we think that the approach and direction to EPA has to include some important time limits, particularly as it relates to dealing with innovative or new uses of chemicals. Second, dealing with covered—I am sorry, dealing with confidential business information is critically important. Intellectual property is key, the lifeblood of the tech sector, and so ensuring that confidential business information is maintained as confidential is critically important to us. And third and final, the issue of preemption is also critically important. We recognize that the States have an important role to play in these processes and in setting standards, at the same time, we develop locally and disseminate globally. And so dealing with 50 or 51 different standards around human health and environmental safety is simply untenable and unworkable for us.

Thank you again for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Mr. Garfield follows:]

Information Technology
Industry Council

Hearing on
"S. 1009, the Chemical Safety Improvement Act"

Testimony of
Dean C. Garfield
President and CEO
Information Technology Industry Council (ITI)

Before the
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
United States House of Representatives

November 13, 2013

Chairman Shimkus, Ranking Member Tonko and members of the Subcommittee:

Thank you for the opportunity to testify at today's hearing regarding Senate bill 1009 – The Chemical Safety Improvement Act.

My name is Dean Garfield and I am the President and CEO for the Information Technology Industry Council, or ITI. ITI is a global trade association representing over 50 of the world's most innovative companies in the information and communications technology sector. Our members have an abiding commitment to sustainability and corporate social responsibility – a commitment we have again demonstrated through our strong leadership to continually improve our processes, supply chains and our products to better protect human health and the environment.

The tech sector is largely a home-grown U.S. industry that has achieved unparalleled global success. Our companies annually spend billions of dollars in the U.S. on research and development, design and manufacturing, and millions of American workers. America's tech sector is defined by innovators, creating dynamic products and services that transform how we all live, work, and play. We're job creators, putting nearly 6 million people to work across American each day. We're growth engines, contributing about $650 billion annually to the U.S. economy -- a figure that expands each year. Our sector's hardware, software and service innovations make the rest of the economy more productive, increase energy efficiency, reduce costs and increase the quality of life for Americans and global populations alike.

Our sector is committed to protecting human health and the environment, and we have realized significant gains, often on a voluntary basis, both with regard to the materials and processes we use to manufacture products, and to those materials that are contained within our final products. We have established and implemented high standards throughout our global supply chains: from the sourcing of minerals used in our products; to the conditions in

our suppliers' facilities; to the ongoing use of more environmentally-favorable materials; to the design of products that are more energy efficient and easier to upgrade; to the foremost private sector product refurbishment and recycling programs.

ITI is privileged to be invited to testify at today's hearing regarding the Toxic Substances Control Act (TSCA) and the Chemical Safety Improvement Act. As many people have noted, TSCA has not undergone substantial change since its enactment in 1976. Over the last several years, however, we have seen major changes in the regulatory frameworks used to oversee chemical safety in countries around the world and in some U.S. states. In that context, it is reasonable for Congress to consider whether TSCA needs improvement.

I can summarize our priorities for TSCA reform as legislation that:

- Meets human health and environmental objectives while also enabling U.S. leadership in technology development, manufacturing and economic advancement;
- Maintains an efficient process for the assessment and management of chemicals that allows the chemical industry to provide downstream industries with the materials they need on a timely basis.
- Provides timely evaluation and approval of new chemicals critical to innovation;
- Directs EPA to evaluate and manage chemicals in a transparent manner that ensures that chemical suppliers and downstream user industries have certainty regarding the use and availability of materials;
- Balances the need to ensure necessary confidential business information (CBI) protections with appropriate access to health and safety information to regulators and the public;
- Establishes a consistent set of standards, whenever feasible, across international and state borders that will allow our industry to design and sell the same product in all of our domestic and global markets.

General Perspectives

ITI and our members support targeted TSCA reforms that are consistent with continued U.S. leadership on technology development, manufacturing and innovation. TSCA is a chemicals management statute, meaning that most ITI members have limited, if any, direct compliance obligations. That said, our continued innovation and ability to manufacture and create jobs in the U.S. rests on continued certainty within the federal chemicals management program, timely approvals of new chemicals, and strong CBI protections for us and for our suppliers. In sum, we need a chemicals management program that can work in practice for EPA, for our sector's materials suppliers, and for our customers and the public. We welcome the opportunity to participate in the dialogue as it evolves.

In general, ITI promotes chemicals management approaches that consider the potential hazard of a chemical as well as the potential exposure associated with a particular use of that chemical. Of equal importance, a strong chemicals management program must rely on sound science and data, including the thorough assessment of the potential environmental, energy and human health impacts of proposed alternative substances. Our sector has experience in other jurisdictions with chemicals restrictions or outright bans based on hazard that yield questionable environmental benefits. In many instances, these results are coupled to the challenges or unintended consequences associated with the available substitutes.

We have reviewed the Chemical Safety Improvement Act that is now under consideration in the Senate. We applaud the efforts by the supporters of that bill to work together across party lines to find areas of common ground. We also agree with other stakeholders that S. 1009 is a reasonable starting point for consideration of how the TSCA program could be improved. In that regard, we would like to identify some specific areas that we think warrant further discussion.

Consideration of "Articles"

As with numerous other sectors of the American economy, ITI and our members have particular interest concerning how a reformed TSCA statute would address articles – the potential regulation of chemical content in components or finished products. The current TSCA allows EPA to apply its import and export provision to chemicals in articles (e.g., machine parts, computers, vehicles, etc.), as well as to chemical substances and mixtures.

Since the beginning of TSCA's implementation, however, the U.S. government has exempted articles from these import/export provisions, while reserving its ability to regulate articles on a case-by-case basis. The Senate bill contains a problematic definition in its import provision that conflates articles with chemical substances and mixtures. We suggest that this definition either be deleted or appropriately rewritten to ensure consistency.

With regard to articles, we recommend that any TSCA reform bill:

- Retain the general article exemptions for import/export that have been recognized for over 30 years. Under this approach, EPA can issue a rule, when necessary, that would apply specific obligations to articles on a case-by-case basis. That authority should be retained for use by EPA in special circumstances.

- Include language that would guide EPA in addressing articles across the statute. Prior to considering articles, EPA should be required to demonstrate that the objective of the action cannot be adequately addressed through action on chemical substances and mixtures alone, and that the presence of the substance in the specific article would significantly contribute to public risks within the U.S.

Regulatory Alignment

We recognize that federal preemption is a challenging issue. The Senate bill would preempt certain types of regulations that the states may take once EPA has designated a chemical as a high or low priority, or has established a schedule for the chemical's safety assessment and determination. Our sector cannot manufacture a unique product for a given state, nor do we sell products on a state-by-state basis. Given that we design for a global marketplace and distribute our products on a regional basis through independent third parties, our sector has struggled in the past simply to meet state-specific product labeling requirements. Unique state-specific product design requirements would be unworkable, so we urge Congress to protect interstate commerce which depends upon consistent regulation across all states.

Confidential Business Information

The Senate bill appears to change the Section 14 criteria that EPA must use to determine what information may be claimed as CBI under TSCA. It is unclear at this point how the CBI protections provided under the Senate bill would differ from the protections currently in place. To be clear, ITI members and our supply chain partners need CBI protections to ensure that we can continue to introduce new materials and protect new uses of existing materials that enable competitiveness, innovation, economic progress and job creation. We support necessary CBI protections, while also recognizing that regulators and the public need appropriate access to relevant health and safety information.

Open Questions

ITI and our members have a number of open questions regarding the approach advanced in S. 1009.

First, the Senate bill would require EPA to conduct a risk assessment of high-priority existing chemicals for their "intended uses." We need clarification as to whether this approach would require EPA to assess all uses of a chemical, including low-risk scenarios, or whether the Agency may focus on significant exposures that account for the chemical's primary risk. This latter approach is the one that EPA currently applies in the TSCA program, and we support its continuation.

Second, the Senate bill rewrites a significant portion of the Section 5 provisions affecting the review of new chemicals under TSCA. The new provisions appear to incorporate elements of EPA's implementation of the new chemicals program, but ITI would need to better understand what the intended changes would accomplish before we can fully comment on this language.

Third, the current standard for Section 6 of TSCA is fully compatible with Presidential Executive Orders that have been in place for decades. These EOs require agencies to evaluate regulatory options for achieving the purpose of a rule, and to assess the costs and benefits of all options considered. The Senate bill would divide EPA's chemical program into a series of discrete steps (i.e., safety assessment, safety determination, risk management action, exemptions). It is not clear when EPA would prepare its Executive Order assessment under this new framework, or how the results of a cost-benefit analysis would be applied during the process.

ITI and our members support targeted TSCA reforms that are consistent with continued U.S. technology leadership, manufacturing and innovation. We welcome the opportunity to continue to participate in this important dialogue.

Thank you again for the invitation to testify today. I would be pleased to answer any questions.

Mr. SHIMKUS. Thank you, sir.

Now I would like to turn to Mr. Andy Igrejas, National Campaign Director of the Safer Chemicals, Healthy Families. Welcome.

Mr. IGREJAS. Thank you very much, Mr. Chairman and Mr. Tonko.

Mr. SHIMKUS. Check your microphone.

Mr. IGREJAS. Thank you. Sorry about that.

Mr. SHIMKUS. That's all right.

STATEMENT OF ANDY IGREJAS

Mr. IGREJAS. Safer Chemicals, Healthy Families is a coalition of 450 health and environmental organizations, industrial unions and steel and automobiles, as well as businesses, some large, some small, from around the country. There is a broad political spectrum, actually, of membership in the organization in the coalition.

We came together in 2009 to achieve reform of the Toxic Substances Control Act, and we agree with the sentiment and we are hopeful that that day could soon be at hand with the legislation that has been introduced, but I would have to say that we believe that legislation is not yet balanced. It needs a lot of work in order to become balanced, and it needs clearer benefits for public health and the environment sooner, and it needs a clearer break with the dysfunctional past of TSCA, that I think has been surfaced in your own analysis and your own oversight of TSCA.

I want to put the focus back on public health because it is that concern, the mainstream health professional and public health community conclusion that, from pediatricians, obstetricians, others, endocrinologists, that chemicals are contributing to the burden of disease in this country; the diseases that affect millions of American families, and TSCA reform is fundamentally a solemn exercise in trying to make progress in preventing that effect.

The groups like the Autism Society, Learning Disabilities Association, breast cancer groups and others who are in the coalition are here because of that, and it is what is driving the public concern that is changing the marketplace and driving the States right now. And so we need to make progress on that, that is very clear. And I think you had the right idea when you started with the examination of what was wrong with TSCA, what didn't work and why. And you saw, I think, in the testimony that the law never really got off the ground, that the procedures and the standards proved to be unworkable, they got tied in knots, EPA, trying to regulate asbestos. When they were finally done, they were thrown out of court, and the law didn't make much other progress. And it is a shame that Mr. Dingell is gone because his amendment is one of the clearer parts of TSCA that did do something; the PCB ban. And because of all that, the fact that TSCA didn't restrict the States turned out to be one of its major blessings, one of its only benefits, because States have been able to make process in the interim.

Nevertheless, we are hopeful that the bill can be improved based on the testimony of the Senators and our own engagement with the Senators' offices and with yourself, being invited here. And I want to highlight a few areas, there are more in the testimony, for the

purposes of helping focus improvement and getting to a more balanced bill.

First is the standard. The core idea of the Chemical Safety Improvement Act that the—is that the standard is fixed in the unreasonable risk standard. We believe that it is not. The attempt to fix it is to apply qualifying language for how it should be used in Section 6, but the standard is also used in other sections of the bill. And the related issue of the least burdensome requirement, while that phrase is excised from the bill, a sort of fraternal twin appears that you have heard Jim Jones reference that has basically the same effect. And the bottom line for us is that the—under the bill, our analysis is EPA could still not ban asbestos under this new bill, and that is a problem.

So I think that baggage of TSCA is something to really think clearly about, and we need to break with it in this new bill. It is otherwise going to weigh down this new bill. The clearest—cleanest way to do that would be a new standard, but if not, if that can't be done, fixing this standard so that it is clearly defined as a health-only standard would go a long way to dealing with this problem.

Another problem that has been mentioned is vulnerable populations and aggregate exposure. Maybe aggregate exposure hasn't been mentioned yet. These are core concepts to the American Academy of Pediatrics' recommendations on reform, and I think they should be embraced more tightly in the bill. The bill mentions them but does not really require them to be dealt with as a fundamental part of reform. And I think if you don't do that, you will be left with safety determinations that simply don't reflect the fact that children, it is just a plain medical fact, are more susceptible to these chemicals than people in heavily-impacted communities are, and that people are exposed to the same chemical from more than one source at a time. And so you need to add up those exposures when you are figuring out what is happening to them, and the protective measures, the risk-management measures, need to reflect that.

So if we don't do that, we will simply be getting the determinations wrong, and they won't really be protecting the public, and I think you want to be able to claim otherwise when we are done with this exercise.

I want to highlight a couple of issues where the bill actually goes backwards and we think does new harm. The first is the issue of frameworks which has been mentioned. The bill requires a lot of new frameworks. It delays the start of the program for several years. We believe that that sounds too much like the old TSCA. We want less red tape put in front of EPA taking action, not more. Also States' rights. That has been mentioned earlier. The bill infringes on them to a great degree in a way that we think goes against the record. I think you noticed in your comments earlier that not a lot of States have taken the fundamental action, but at least they have made progress on chemicals while the Federal Government was tied up in red tape. And our fundamental interest in preserving States' ability, both the progress they have made and their ability to make new progress, really is Mr. Barrow's hunting dog analogy that no one expected TSCA to not work out the way

that it did, and any problems in this new law, whether the funding or anything else at implementation, we want that safety valve that the States can still take action and can still make progress.

So I will mention the other provisions that are in my—just briefly. It is CBI, I think they need a new balance on CBI, deadlines, the funding mechanism, broader authority to require testing, but the bottom line position is all of these issues, we think, can be solved. Some of them can be solved quite simply, but our main message is that they really have to be solved for this bill to be balanced.

So thank you very much.

[The prepared statement of Mr. Igrejas follows:]

House Energy and Commerce Committee, Environment and Economy Subcommittee
Hearing on Chemical Safety Improvement Act
November 13th, 2013

One Page Summary of Testimony for Andy Igrejas, *Safer Chemicals, Healthy Families*

1. The Chemical Safety Improvement Act presents an opportunity for TSCA reform, but it falls short of the critical elements needed for reform to be meaningful and credible. The legislation can be fixed, however. We urge Congress to focus on the critical changes.

2. Overall, the CSIA fails to learn the lessons of TSCA itself. The current program quickly ran aground due to an unworkable safety standard, overly burdensome procedures and litigation. Its only concrete achievement was banning PCBs and its save grace was that it did not unduly restrict states.

3. While the intent of the CSIA is to "fix" TSCA's standard, that intent is not realized in the language. The safety standard should be redefined to clarify that it is a risk-only standard. Section 6 should be redrafted to simplify and clarify the role of cost-benefit analysis and to clearly end the "least burdensome" requirement.

4. Safety determinations for existing chemicals under CSIA do not clearly incorporate protection for vulnerable populations, especially children and pregnant women, nor would they clearly require aggregate exposure assessment. This may be another area where intent and language do not match up, but these are critical elements needed for any reform measure.

5. The ability to require testing by order rather than rule is an improvement, but other provisions on information undermine this improvement. The CBI provisions be amended to remove the grandfathering of existing claims and more work is needed to strike a balance on the issue of chemical identity.

6. The provisions requiring new frameworks and guidance in Sections 4 and 6 will substantially delay the new program and will likely create new handles for litigation. They should be removed or substantially paired down and clarified.

7. The pre-emption provisions would unduly restrict states, ignoring that key lesson of TSCA.

8. The CSIA needs deadlines, minimum requirements, and a funding mechanism to ensure timely implementation.

9. In general, the legislation must be rebalanced to produce timely and clear health and environmental benefits and reduce the risk of a repeating the paralysis of TSCA.

Testimony on the Chemical Safety Improvement Act (S.1009)

House Energy and Commerce Committee
Environment and Economy Subcommittee
November 13, 2013

Andy Igrejas, Director
Safer Chemicals, Healthy Families

Thank you, Chairman Shimkus, Ranking Member Tonko and members of the Committee. My name is Andy Igrejas and I'm the Director of Safer Chemicals, Healthy Families, a broad coalition of organizations and businesses[1] dedicated to reforming our nation's chemical policies to better protect public health and the environment. I'm very thankful for the opportunity to address the committee as it considers reform of the Toxic Substances Control Act (TSCA).

The focus of today's hearing is S. 1009, the Chemical Safety Improvement Act (CSIA). The Senate bill has raised hopes that reform can be enacted in this Congress. We share those hopes. At the same time, there are standards that any reform must meet to be credible and meaningful. As drafted, the CSIA does not meet those standards. We offer the following critique of the legislation in a constructive spirit with the hope that it can inform Congress's work.

In previous hearings the committee began the process of understanding what didn't work in TSCA and why and of identifying the critical fixes needed in any reform. Congress can craft a law that will enjoy broad support from the health and environmental community if it focuses tightly on the most critical elements to achieve the clearest possible protections for public health and the environment. I hope my testimony suggests a path forward.

Key Lessons of TSCA

As previous testimony has shown, TSCA failed for a variety of reasons. The standard in the bill proved impossible to meet. Unlike other environmental and public health laws, it was not a strictly risk-based or health-based standard. The standard bound up consideration of the risks of a chemical with the evaluation of its benefits and the costs of any proposed restrictions. The law also required EPA not merely to choose proportional risk management measures, but to demonstrate it had chosen the "least burdensome" of those measures. It made it difficult for EPA to require the development of health and safety information on a chemical. It allowed companies to claim information confidential without justification. It did not set clear deadlines or timelines for EPA action. Its procedures were cumbersome and some of its terminology vague, leading to fatal delays and litigation. In retrospect, TSCA's only clear achievement was the ban on PCBs and its saving grace was that it did not unduly restrict the states. In the 36 years of federal dysfunction the states have stepped forward to fill the gap.

The fundamental problem with the CSIA is that it fails to learn from these lessons. Though the intent may be otherwise, as drafted the CSIA practically invites litigation, delays action on most chemicals, continues to constrain the development of health and safety information, and allows critical information to be hidden from the public. But this time it would also restrict the states even in the absence of meaningful action from the federal government.

The Safety Standard

A core idea of the CSIA is that it "fixes" TSCA's standard rather than imposing a new standard such as "reasonable certainty of no harm" as proposed in previous reform legislation. At its most basic level, fixing the standard means changing it to be a risk-based standard, rather than one that balances the risks and benefits and also requires EPA to choose the "least burdensome" regulatory approach. It is the commingling of these considerations that the court cited in blocking EPA from regulating even asbestos, a substance with devastating health impacts that are beyond argument.

The CSIA has language in Section 6 saying that the safety determination for existing chemicals should be made based on risk, but because of the way it is drafted the cost-benefit considerations are not fully separated and the "least burdensome" requirement is effectively retained for bans and phase outs. While the intent of the bill may be to require a risk-only determination in this section, that intent is not realized. In fact, our reading of the legislation is that EPA would still not be able to ban asbestos under the section as drafted.

But there is the additional problem that the "unreasonable risk" standard is also invoked in Sections 4 and 5 where there is no qualifying language suggesting a new meaning. In Section 4 EPA is directed to identify chemicals as "low priority" based on a determination that they are "likely to meet the safety standard." Those chemicals are set aside for no further action or scrutiny. In Section 5 the EPA is directed to apply the same test to a new chemical before it is allowed on the market. This is one of the bill's major selling points- that it imposes a safety screen of some kind on new chemicals for the first time. However, since "unreasonable risk" has such a clear meaning in the legislative history and case law of TSCA, it would almost certainly have the same old meaning, and therefore the same old problems, in these sections.

The simplest way to avoid these problems is choosing a different standard that signals a clear break with TSCA, such as "reasonable certainty of no harm" which is currently used in the pesticide program. If the legislation continues to use "unreasonable risk" it should be clearly re-defined in the definitions section of the bill to be explicitly health-only. That clear break would end the ambiguity anywhere the term is used in the bill and reduce the risk of litigation. Section 6 should also be redrafted to truly end the "least burdensome" requirement and simplify the cost benefit considerations for risk management measures.

Safety Determinations

Recent National Academy of Sciences[2] reports, the American Academy of Pediatrics[3], and the broad public health and environmental community agree that safety determinations should

protect vulnerable populations and account for the aggregate exposure to a chemical. Though grounded in science, both concepts also make common sense and are relatively easy to understand. They were at the core of the bipartisan reform of pesticide law, the Food Quality Protection Act (FQPA) of 1996. Neither concept is adequately reflected in the CSIA, though they are mentioned in ways that suggest some intent to incorporate them.

Vulnerable populations refers to the fact that a given chemical will affect me- as a relatively healthy 200lb adult male in Washington, DC- differently than it affects a child, a pregnant woman, or someone who lives or works in a heavily contaminated environment. Many chemicals, particularly those that mimic hormones, have substantially more impact on the developing fetus or child than on an adult.[4] The vast body of peer-reviewed science on this subject over the last twenty years has helped put chemical reform on the national agenda. A 1993 National Academy of Sciences study, *Pesticides in the Diets of Infants and Children*, found that a failure to account for vulnerable populations meant that EPA decisions about pesticides did not protect children from exposure to the pesticide residues on food. Congress responded with the FQPA in 1996 to ensure that they did. It would be odd for Congress, after all these years, to reform our chemical policies in ways that did not provide a similar assurance for chemicals. Vulnerable populations should be defined in the legislation. Safety assessments should be required to identify them for a given chemical, and any risk management measure should be required to protect them.

Aggregate exposure is a fancy term for the basic fact that we are often exposed to the same chemical from multiple sources. That means that the dose of the chemical that we receive is bigger than the dose from any one exposure, in the same way that taking three pills of a prescription drug represents a bigger dose than one pill. A pregnant woman, for example, might be exposed to the same chemical from multiple consumer products in her home, a process at her workplace, and- if the chemical is also a pollutant- from the air or water. If safety assessments don't take the aggregate exposure into account, they will simply be wrong. They will not reflect what is happening in the real world and the resulting risk management measures won't make a difference in the real world. The legislation should require EPA to assess the aggregate exposure to a chemical unless it determines that any vulnerable populations it identifies are not exposed to the chemical from more than one source.

Our coalition prefers the "reasonable certainty of no harm" standard in part because it incorporates these concepts automatically given its history in the pesticide law. If Congress retains the "unreasonable risk" standard in the legislation, the safety determinations must include vulnerable populations and aggregate exposure as core concepts. (This also could be done in a new definition of "unreasonable risk.") Otherwise, Congress will not be able to claim that the legislation protects pregnant women and children and heavily contaminated communities from chemicals as they are actually used.

Testing and Information Requirements

The CSIA allows EPA to require testing on an existing chemical by order rather than by the more cumbersome rule-making process. That is a significant improvement for which its authors deserve credit. At the same time this improvement is constrained by the fact that EPA can require testing only for existing chemicals under the bill if it has designated them as high-priority. That creates a few problems.

First, it means that EPA can only prioritize chemicals based on existing information, rather than any new testing data. The information available for most chemicals is relatively limited (a legacy of TSCA's overly burdensome process for testing.) That, in turn, means that a chemical could be designated as low-priority based on inadequate information. Under the bill, these chemicals are then effectively set-aside forever at both the federal and state level, unless new information becomes available. It is unclear where that information would come from. Industry would have no incentive to develop it, and EPA would not be allowed to order it under the bill. In addition, if EPA has to put anything that it thinks needs some testing in the high-priority category it will certainly slow down that process. An obvious solution is to allow EPA to order testing for purposes of prioritization, not just for purposes of a safety determination, and to require adequate information for a low-priority designation.

In addition, the CSIA requires EPA to tier testing requirements in an overly rigid way. A chemical would have to raise a red flag from a screening level test before EPA can order a more extensive test. There are not effective screening level tests that predict some of the health endpoints about which the public is most concerned. Where these endpoints are a concern, the EPA should be able move straight to the more relevant test. The tiered testing requirements in the bill should be eased to ensure that needed tests aren't prevented.

Finally, the CSIA takes away EPA's ability to require testing for new chemicals. The way it is drafted suggests that change may have been inadvertent, but this authority should be restored.

Confidential Business Information

The public interest community and most of regulated industry have agreed for some time that TSCA's provisions for CBI are too often abused. In addition, the burgeoning "secret inventory" of chemicals undermines the transparency of the program. The absurd consequence is that you can see there is a chemical on the inventory that causes cancer, you just can't find out which chemical.

The CSIA creates new rules of the road for justifying CBI claims that are an improvement, but it strangely grandfathers in existing claims, including those whose abuses fueled calls for reform. The grandfathering should be removed. In addition, the CSIA enshrines the concept of a secret inventory in the law for the first time. Further debate and discussion are needed to find a solution on the issue of chemical identity that does not threaten public health and the environment.

"Frameworks" and Science Guidance

There are six subsections in Section 4 and two in Section 6 of the CSIA that require the EPA to develop new "frameworks", policies and guidance on both procedures for the program and scientific questions like evaluating the reliability of data. These policies are also subject to notice and comment and judicial review. Simply completing these frameworks on the most optimistic schedule would take several years. If EPA is prevented from getting started evaluating chemicals until these policies are in place it will lead to substantial delay in the entire program.

In addition, this section of the bill uses various terms of art in ways that are mostly undefined and which will encourage litigation over the ambiguities. In at least one instance the bill takes a

stand on a particular science question that contradicts the National Academy of Sciences recommendations.

These sections of the legislation could simply be eliminated. The EPA already has guidance and polices on most of the questions – like prioritization and assessment methodologies. At the very least these sections should be consolidated with careful attention to avoiding new handles for litigation or unacceptably delaying the start of the new program. If science guidance is needed, it should reflect, rather than contradict, the recommendations of the National Academy of Sciences.

State Pre-emption

One of TSCA's only clear successes is that it allowed states to develop their own chemical policies and restrictions unless they conflict with a federal regulation. Even then, it allowed states to seek a waiver for their own restrictions or to ban a chemical outright. Since the TSCA program never really got off the ground, states have played the leading role in regulating chemicals over the last 36 years. Many states have banned particular chemicals of concern-like mercury, cadmium and bisphenol A- from particular categories of products. A handful - California, Maine, Washington, and Minnesota - have developed more comprehensive policies that address broader classes of chemicals.[5] These policies have improved public health and environmental quality.

CSIA would pre-empt state restrictions on a chemical at the point at which EPA prioritizes the chemical as either High or Low. Low priority chemicals are those that EPA is setting aside based on a review that is, by definition, short of a full safety determination. This more cursory review does not justify that level of protection for a chemical. For high priority chemicals, on the other hand, it could be years between the prioritization of the chemical and the decision that it is either safe, or that it is unsafe and requires risk management measures. In the meantime, states would be prevented from taking action on what are, by definition, the riskier chemicals. The proposed new waiver process for states is overly cumbersome compared to the existing one. The states' ability to co-enforce federal requirements is removed. Finally, while an attempt has been made in the bill to preserve state warning and information requirements, which have been some of the most effective, the language ultimately does not protect them.

The more protective approach to states' rights in the current TSCA largely worked as intended. States were allowed to move forward even as the federal program became bogged down in ways that surely none of its authors intended. Congress should apply that lesson to the CSIA.

Deadlines, Minimum Requirements, and Funding

One of the lessons of TSCA is that it lacked deadlines or goals for how many existing chemicals should be reviewed or how long assessments should take. The new chemicals program, on the other hand, had clear deadlines for how quickly EPA had to respond to a pre-manufacture notice. As a result, most of the activity at EPA under TSCA has been in the new chemicals program. Also, other laws administered by the EPA generally had deadlines for listing pollutants or making decisions, pushing TSCA's existing chemicals program to the back of the line in a bureaucratic environment of limited resources.

The CSIA repeats this mistake. It should be amended to add deadlines for critical policy decisions and for the minimum number of chemicals assessed, either per year, or over some

longer timeframe. Reform should also contain a new source of dedicated funding for the program, such as a user fee. Appropriate deadlines and work requirements would drive action at the agency and help both Congress and the public to hold the agency accountable.

The Low Priority Category

Finally, we would urge the Committee to consider whether the legislation should have a low-priority category at all. The goal of reform should be to protect public health and the environment from the risks posed by chemicals. Public confidence will follow if that goal is being met and benefits to the business community will follow on top of that. A modest but credible program will still produce tangible results.

The low-priority category in the bill adds a level of murkiness to the program that will likely undermine its credibility. For high priority chemicals- if all the appropriate fixes are made- the public will know that a chemical is either safe or that its risks are being adequately controlled. Low priority chemicals, however, are effectively being treated as safe even though they haven't really been found to be safe. Furthermore, EPA resources will be diverted into deciding what goes into this murky category rather than focused where they should be: taking action on the riskiest chemicals.

Earlier, I proposed changes that limit the damage from this category- requiring adequate information, breaking the link to pre-emption, clarifying the standard, etc. But with limited resources likely to be the norm for the foreseeable future, Congress should consider focusing those resources on a single category of priority chemicals.

Conclusion

This is not an exhaustive list of either the problems with the CSIA or its positive attributes, but it does provide the committee with the areas of the bill that we believe require the most attention. In general, the bill needs a substantial reworking and rebalancing in favor of delivering clearer health and environmental benefits sooner and reducing the risks of paralysis and delay. There are provisions from previous reform proposals, such as expedited action on persistent bio-accumulative toxins (PBTs) and "hot spot" communities that would help effect such a rebalancing if incorporated. I've focused my testimony instead on the core areas within the framework of the CSIA and where we see them falling short of the critical elements needed for reform to be meaningful and credible. We hope Congress will consider these recommendations and craft legislation that provides the public with the appropriate oversight of chemicals that is long overdue.

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[1] Saferchemicals.org/about/who.html

[2] National Research Council, *Science and Decisions- Advancing Risk Assessment* (2009), National Acadamies Press

[3] "Policy Statement Chemical-Management Policy: Prioritizing Children's Health," April 25th, 2001, *Pediatrics,* American Academy of Pediatrics.

[4] https://www.endocrine.org/~/media/endosociety/Files/Publications/Scientific%20Statements/EDC_Scientific_Statement.pdf

[5] http://www.saferchemicals.org/PDF/reports/HealthyStates.pdf

Mr. SHIMKUS. Thank you.

And now I would like to turn to Wendy Wagner, Joe A. Worsham Centennial Professor at the University of Texas School of Law. Welcome and your statement, you have 5 minutes.

Ms. WAGNER. Thank you. Thank you, Mr. Chairman, Ranking Member Tonko and——

Mr. SHIMKUS. And you may want to pull that microphone a little bit closer.

STATEMENT OF WENDY E. WAGNER

Ms. WAGNER. That is nice. I have an Ethel Merman voice, so it is good to need a microphone.

Thank you, Mr. Chairman and Ranking Member Tonko and the members of the subcommittee. I am pleased to testify here today.

My focus is going to be a little bit different than some of the other panelists. I am going to focus on the good science provisions of Senate Bill 1009.

I have studied the use of science by regulatory agencies, particularly EPA, for over 20 years, written a couple of books, dozens of articles, I have also done some empirical analyses. And based on this extensive study, when I look at the good science provisions in Senate Bill 1009, I see that they are just as likely to undermine the scientific rigor of EPA's decision making as to enhance it. And, in fact, I think if you show the good science provisions to the National Academies, they would identify some fundamental problems with the way the bill proceeds, particularly with the idea that the scientific information available to EPA should be restricted by terms set by Congress with regard to what constitutes acceptable science.

Now, I raise a number of issues in my written testimony. I am just going to highlight three here today.

The first—there are over 40 pages by my count of good science provisions in the bill, but I am not sure what the underlying problem is that those 40 pages are trying to address. There are really serious problems with TSCA and EPA's implementation of TSCA, to be sure. I am not aware in the literature though of problems with EPA's failure to use the best available science in its regulation.

Second, as I read it, the bill reduces rather than enlarges the information available to EPA to regulate using this best available science gateway with the three-prong requirements. There are a number of features of the best available science. Just to take one as an example, according to the best available science, all the information used by EPA in its safety assessments and safety determinations needs to have peer-reviewed data. Now, even with a liberal interpretation of what peer-reviewed data is, and there could be a lot of disagreements about what that is, even with a liberal interpretation, I read that as having the potential to exclude a lot of industry submissions over the last 40 years. The substantial risk reports under AE, for example, I am not sure those would clear just that one barrier in best available science. Even the test data provided by the manufacturers over the last 30 years, I am not sure that would clear some of the best available science requirements. If EPA wants to bring these industry submissions up to the stand-

ards of best available science, it is my reading of the bill that the burden would be on EPA. They would need to make sure the industry submissions meet all the various requirements.

More to the point, the problem with TSCA has been the EPA doesn't have enough information to assess chemicals. It can't regulate chemicals if it doesn't have this information. So legislation that actually further restricts the information available to EPA to do assessments seems to me to be moving in exactly the wrong direction.

I am also not sure what the scientific pedigree is for this best available science provision written in the Senate Bill 1009. It doesn't align with the National Academy's reports I have seen, at least.

Third, the good science provisions, and this has come up before, are loaded with ambiguities. Lawyers, including the students I teach, have a term for this. When you have a mandatory provision that is very ambiguous, it creates what is called an attachment point, because high stakes, litigious groups can latch onto those attachment points and hold the Agency's feet to the fire in litigation. By my count, the good science provisions in Senate Bill 1009 contain dozens of attachment points. The administrative literature also reveals that when an agency has a statute ladened with all these attachment points that invite litigation, not only will be—it be embroiled in litigation, but it is likely to seek to compromise with the high-stakes, most-litigious groups. It is actually not necessarily either because the agency is captured, it simply wants to get some rules through the process, so it needs to engage in these compromises. One of my worries when I look at this is who will these high-stakes litigious groups be. I am concerned it won't be the best manufacturers in the United States who make the safest and most effective chemicals. The manufacturers taking advantage of these attachment points, I am concerned, will be the manufacturers that make the least effective and most toxic chemicals.

Now, despite the fact that these good science provisions are loaded with attachment points that are likely to lead to litigation and delay, as you have heard, except with one exception, I think, there are no deadlines at all in the statute—I am sorry, in Senate Bill 1009, not the statute. That was not a fraudulent slip. The bill also provides absolutely no mechanisms for ensuring the transparency of whatever side deals in compromises take place.

In my view, the basic goal of chemical policy should be to get safer, more effective chemicals out of our manufacturers. The bill does not provide these kinds of incentives.

If the bill became law as-is, I don't see any possibility of a race to the top among the manufacturers in the United States who make chemicals. Instead, the bill is ladened with a maze of procedural requirements for EPA, with landmines for litigation at every turn. I think we can do better.

Thank you. I look forward to your questions.

[The prepared statement of Ms. Wagner follows:]

TESTIMONY OF

WENDY E. WAGNER
Joe A. Worsham Centennial Professor
University of Texas School of Law

on

S. 1009: The Chemical Safety Improvement Act

Energy & Commerce Committee's
Subcommittee on Environment and the Economy
U.S. House of Representatives

November 13, 2013

One page Summary of Wagner Testimony

My testimony will focus on the various good science provisions in S.1009 and how they are likely to impact EPA's use of science. I will make the following points in my remarks:

1. The Senate bill contains dozens of unprecedented requirements that limit the scientific evidence EPA can consider when developing regulations and how this evidence can be used. Yet despite the detailed level of scientific prescription in the Bill, it is not clear what problem the Bill is trying to fix. While there have been many failures associated with the Toxic Substances Control Act (TSCA) over the years, they are generally not connected to EPA's failure to make use of the best available science when promulgating regulations.
2. By contrast, there is broad consensus that the primary problem crippling EPA's regulatory efforts under TSCA is the dearth of information about chemicals. The Senate Bill not only appears oblivious to the scarcity of toxicity and related information on most chemicals, but may aggravate the problem by preventing EPA from considering research that has the potential to inform EPA's assessments in scientifically acceptable ways.
3. The various good science requirements and procedures are also loaded with ambiguities, creating numerous "attachment points" that present opportunities for a steady stream of legal challenges to EPA's rules. If history is any guide, entities with the most at stake (e.g., manufacturers of the least effective and least safe chemicals) will use these attachment points to delay EPA's implementation or force EPA into negotiations before, during, or after a rule is published. Senate Bill 1009 also lacks enforceable legislative deadlines to counteract this inevitable delay for most provisions. The Bill also makes fails to provide procedural protections that will prevent or at least illuminate these compromises that fall outside the formal processes and out of the public eye.
4. Protracted delays in implementation, with corresponding, potentially high costs to protection of the public health, seem inevitable from the cumulative problems with the good science provisions in S. 1009.
5. Chemical regulation will be effective only if it provides incentives for the manufacture of safer and more effective chemicals. The Senate Bill does not provide these incentives.

My name is Wendy Wagner. I hold the Joe A. Worsham Centennial Professorship at the University of Texas School of Law, where I teach courses in Environmental Law, Law and Science, and Torts. In addition to my academic responsibilities, over the last ten years I have served on several National Academies of Science committees, the Bipartisan Policy Center Committee on Regulatory Science, and as a consultant to the Administrative Conference of the U.S. (ACUS) on a study of the agencies' use of science. I am also a founding member scholar of the Center for Progressive Reform. I have published dozens of articles on regulatory science and two books, *Bending Science: How Special Interests Corrupt Public Health Research* (with Tom McGarity 2008) and *Rescuing Science from Politics* (with Rena Steinzor 2006).

I am pleased to testify on Senate Bill 1009, entitled the Chemical Safety Improvement Act (CSIA). I have been asked to analyze how the Bill might affect the EPA's ability to find and use scientific information. My views are wholly my own and are not necessarily those of the University of Texas or other organizations with which I am affiliated.

As I discuss in more detail below, while I applaud the Senators' goal of attempting to ensure that the science that informs the regulation of chemicals is rigorous, I have a number of questions and concerns about the approach taken in the bill.

I. The Good Science Requirements in S.1009 impose unnecessary restrictions on the types of Scientific Evidence that EPA can Consider and How it Analyzes that Evidence

The Chemical Safety Improvement Act provides a number of detailed requirements that govern EPA's use of science in chemical regulation. These constraints

impact the type of information EPA can consider (the inputs) and the processes by which EPA synthesizes the evidence (the processes).

On the input side, the Chemical Safety Improvement Act limits the evidence EPA can consider by demanding that EPA may use only the "best available science" in conducting chemical safety assessments and determinations. This "best available science" provision thus operates as a gateway that filters the information available to EPA to regulate chemicals. Moreover, in CSIA, "best available science" is defined as science that ''(A) maximizes the quality, objectivity, and integrity of information, including statistical information; (B) uses peer-reviewed and publically available data; and (C) clearly documents and communicates risks and uncertainties in the scientific basis for decisions.'' Section 3(2). Each prong of this three part test must be met. The test is thus much more restrictive than best available science requirements contained in the Endangered Species Act, the Safe Drinking Water Act, and the Information Quality Act (and the Office of Management Budget's IQA guidelines).

CSIA also sets forth a series of new, detailed analytical requirements that specify how EPA should synthesize the qualifying evidence. These procedures serve as prerequisites that EPA must fulfill before it can conduct safety assessments or regulate chemicals. An incomplete list of these new procedural requirements include the: 1) development of a "structured evaluative framework" before initiating its chemical oversight work; 2) publication of criteria for evaluating all data and information on which it relies to make any decision; 3) establishing a risk-based screening process for designating chemicals high or low priority for review; 4) development of a strategic plan to promote the development and implementation of alternative test methods and to

promote non-animal tests; and 5) promulgation of procedural rules governing safety assessments EPA will conduct for each "high priority" chemical.

Even EPA's pursuit of additional research must pass through additional hoops. If EPA determines additional data is required, it must first establish there is a need for the data and provide an opportunity for interested persons to submit the additional information. By contrast, the analytical and evidentiary demands placed on the manufacturers who sell the suspect chemicals and have superior information about their risks and benefits are negligible in the Bill, and these requirements are conditioned by close attention to the costs of testing.

By my count, at least forty pages of Senate Bill 1009 are dedicated to developing these legislative constraints on the types of evidence EPA may consider (the inputs) and how it must use this evidence (the process). This level of detailed legislative prescription is unprecedented to my knowledge. The cumulative effect of these requirements seems likely to cause significant delays in implementation and a string of unintended consequences that could product regulatory results quite different from those sketched out in the Bill's opening goals.

II. It is not Clear what Problem the Elaborate Good Science Requirements are Intended to Fix; at the same time, these provisions threaten to make other, well-known problems associated with TSCA considerably worse

Given this unprecedented level of scientific legislative prescription, one would expect that there would be a large literature documenting problems with EPA's scientific analyses in implementing the Toxic Substances Control Act (TSCA).[1] But in my

[1] There is a documented problem with the quality of private research that informs regulation, at least in cases when a sponsor contractually controls the research. Since this

research, I could not identify the underlying problems with EPA's implementation of TSCA that justify this ambitious set of new requirements.[2]

The literature does reveal a central and noncontroversial reason for the failure of TSCA – the lack of basic toxicity information on chemicals and the tendency of this regulatory program to perversely create incentives that perpetuate this ignorance.[3] Virtually every prominent expert panel convened to consider the topic has expressed alarm at the dearth of basic toxicity information on chemicals in commerce.[4] For

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problem is largely ignored in the good science of provisions of Senate Bill 1009, as discussed in Part IV.A., however, it does not appear to be among the problems the Bill attempts to fix. This particular problem is also one that occurs very early in the production of research, not in EPA's own analysis of the available information; the latter is the primary focus of S. 1009.

[2] *See* COMM. TO REVIEW THE OMB RISK ASSESSMENT BULLETIN, NAT'L RSEARCH COUNCIL, SCIENTIFIC REVIEW OF THE PROPOSED RISK ASSESSMENT BULLETIN FROM THE OFFICE OF MANAGEMENT AND BUDGET 6 (2007). Specifically, the NRC noted:

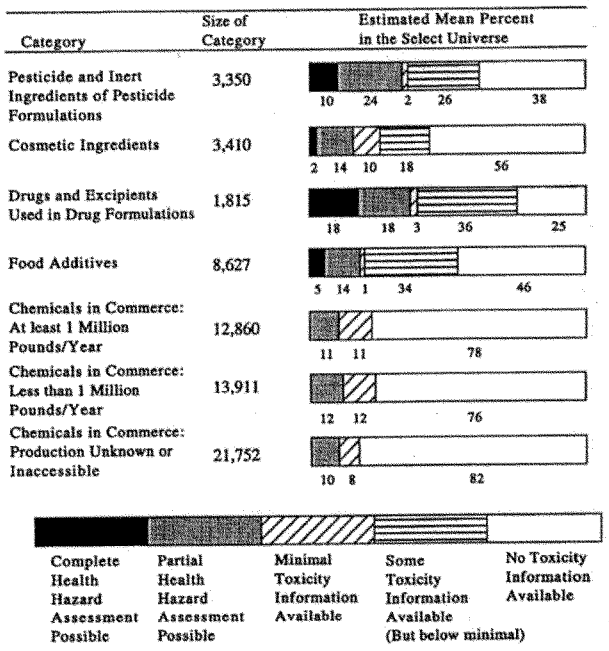
> Perhaps the most glaring omission is the absence of criteria and information for gauging the benefits to be achieved by implementing the bulletin (that is, a benefit-cost analysis). Although OMB has implied that the agencies currently do not meet the standards that it seeks to establish, it has not established a baseline of each agency's risk assessment proficiency, including the extent to which generally satisfactory and high-quality risk assessments are produced or how some agencies fall short of the specified standards. Specifically, OMB has not established which agencies do not appear to know what good practices are and which agencies do not have the ability, resources, or incentives to meet the standards. Similarly, OMB has not identified the costs that could be encountered in implementing the bulletin. Thus, OMB has not determined the impact of the bulletin on federal agencies.

[3] *See, e.g.*, John S. Applegate, *The Perils of Unreasonable Risk: Information Regulatory Policy and Toxic Substances Control*, 91 COLUM. L. REV. 261, 310-13 (1991); Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1813-17 (1989).

[4] *See, e.g.,* NATIONAL RESEARCH COUNCIL, GRAND CHALLENGES IN ENVIRONMENTAL SCIENCE (2000); NATIONAL RESEARCH COUNCIL, BUILDING A FOUNDATION FOR SOUND ENVIRONMENTAL DECISIONS (1997); NATIONAL RESEARCH COUNCIL, REVIEW OF EPA'S ENVIRONMENTAL MONITORING AND ASSESSMENT PROGRAM: OVERALL EVALUATION (1995); NATIONAL RESEARCH COUNCIL, RESEARCH TO PROTECT, RESTORE AND MANAGE

example, as of 1984 *no* toxicity testing existed for more than *eighty percent* of all toxic substances used in commerce, and by 1998, at least one-third of the toxic chemicals produced in the highest volumes still failed to satisfy minimal testing standards recommended by an international expert commission.[5] See bar chart.

TOXICITY TESTING INFORMATION AVAILABLE ON SEVEN CATEGORIES OF CHEMICALS



NRC, TOXICITY TESTING (1984), at page 118 fig.2.

THE ENVIRONMENT (1993); STEERING COMM. ON IDENTIFICATION OF TOXIC AND POTENTIALLY TOXIC CHEMICALS FOR CONSIDERATION BY THE NAT'L TOXICOLOGY PROGRAM, NAT'L RESEARCH COUNCIL, TOXICITY TESTING: STRATEGIES TO DETERMINE NEEDS AND PRIORITIES (1984).

[5] *See, e.g.*, ENVIRONMENTAL DEFENSE FUND, TOXIC IGNORANCE (1997); Bureau of National Affairs, *Testing: CMA more optimistic than EDF and lack of data for 100 chemicals*, 230 Daily Environment Report A-4 (Dec. 1, 1997); Environmental Protection Agency, Office of Pollution Prevention and Toxics, *What do we really know about the safety of high production volume chemicals?*, 22 Chem. Reg. Rep. (BNA) 261 (1998).

Senate Bill 1009 seems curiously oblivious to this well-known failure of TSCA. Instead, its elaborate new provisions are positioned to aggravate the pervasive ignorance surrounding chemicals. The best available science requirement in CSIA, by definition, limits the evidence that EPA can consider in conducting safety assessments and safety determinations, leaving it with less information to assess chemicals than is currently the case under TSCA. Such information filtering might not be problematic in data-rich areas, like the setting of standards for criteria air pollutants, but in chemical regulation, the best available science requirements may filter out so much research that EPA is left empty-handed. For example, the limited test data that EPA has acquired over the years under its test rule authority may not meet this "best available science" requirement since that research is generally not published, does not appear to be peer reviewed, and the data may not be publicly available. Most substantial risk reports required under Section 8(e) of TSCA would also seem likely to fail the "best available science" requirements, since this manufacturer-supplied information does not appear to be peer reviewed and again, in some cases, the raw data is not publicly available.[6] It seems paradoxical that Congress would require manufacturers to alert EPA to substantial risks from their chemicals, many of which are badly under-tested, but then bar (or at least significantly impede) EPA from considering this same, seemingly relevant information in conducting its safety assessment.

In fact, given EPA's dependence on private research to inform its oversight of chemical safety, this best available science hurdle could even be used perversely by manufacturers to obstruct the agency from using their own in-house research and data

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[6] These individual reports are posted at http://www.epa.gov/opptintr/tsca8e/index.html .

when that research suggests worrisome risks. Manufacturers who discover that their chemicals are unduly toxic, for example, could attempt to slow or even exclude these damaging studies by ensuring the research is not peer reviewed or publicly available. In such cases, it would be up to the EPA, using its scarce resources, to subject this research to the necessary peer review and data disclosure requirements.

CSIA also handicaps EPA's effort to acquire new information by adding still more procedural requirements to EPA's ability to demand new test data. In the nearly thirty years of regulatory authority, EPA has issued testing mandates for only about 200 chemicals.[7] Most of the remaining chemicals, roughly 80,000 chemical substances, are effectively unrestricted and often unreviewed with regard to their health and environmental impacts.[8] The primary explanation for this apparent underutilization of EPA's test rule authority is TSCA's requirement that EPA must first making a regulatory finding that the chemical "may present an unreasonable risk of injury to health or the environment" as a prerequisite to requiring more testing.[9] Although CSIA does eliminate this Catch 22 in EPA's test rule authority, it appears to replace one problem with another by demanding that EPA establish that the data is needed as a condition to requiring toxicity testing, as well as imposing other constraints on EPA's test authority. Like the "best available science" restriction, these new prerequisites do not seem destined

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[7] *See, e.g.,* U.S. GOV'T ACCOUNTABILITY OFFICE, CHEMICAL REGULATION: OPTIONS EXIST TO IMPROVE EPA'S ABILITY TO ASSESS HEALTH RISKS AND MANAGE ITS CHEMICAL REVIEW PROGRAM 18 (Report No. GAO-05-458, 2005), available at http://www.gao.gov/new.items/d05458.pdf [hereinafter GAO, OPTIONS].

[8] For the total chemicals in EPA's TSCA inventory, see http://www.epa.gov/opptintr/newchems/pubs/invntory.htm. EPA estimates that for new chemicals, only 15 percent of the premanufacture notices contain any information on health and safety testing. *See, e.g.*, GAO, OPTIONS, at 12.

[9] *See* TSCA, § 2604(e).

to expedite EPA's ability to acquire more toxicity research from manufacturers and may ultimately impose more limitations on EPA's ability to acquire new data as compared with TSCA.

III. The Good Science Provisions are Rife with Ambiguities that invite litigation and are likely to significantly delay implementation and lead to invisible compromises between EPA and high stakes groups

The "best available science" and related analytical prerequisites are not simply benign, motherhood and apple pie provisions; instead they present real risks of impeding agency regulation, with the attendant loss of health protection that follows from this obstruction.

A. The Bill Creates Dozens of New Attachment Points for Litigation brought by opponents of regulation

Because the bill imposes dozens of new requirements on EPA, each of which is afflicted with its own set of ambiguities, there will be no shortage of disagreement about what these new prerequisites and requirements mean. As is the case with most regulatory programs, these disagreements will generally be resolved through litigation. Courts will referee the acceptable meaning of these ambiguous terms and procedures, and the litigation will be brought, or at least threatened, by the high stakes players who have the most to lose from added regulatory oversight. Since the standard for judicial review is the potentially higher "substantial evidence" standard, moreover, EPA may face a less deferential judicial panel in the courts' review of its interpretation as compared to the "arbitrary and capricious" standard of the Administrative Procedure Act (APA).

The "best available science" requirement is illustrative of the nature of these attachment points that afflict the good science provisions in Senate Bill 1009. As mentioned, the best available science requirement imposes three mandatory tests for the evidence EPA is able to consider in assessing and regulating chemicals. Since EPA will presumably seek to interpret these exclusionary provisions generously, its resulting interpretations are likely to spark significant litigation. It is important to note, too, that since the "best available science" provision serves as the gateway for all evidence that may be considered by EPA under Section 6 (and perhaps also under Section 4, depending on how you read the requirements), EPA will not be able to sidestep these ambiguities in the "best available science" definition, but instead must confront them head-on.

Senate Bill 1009 specifies, for example, that "best available science" is only science "that uses peer-reviewed and publicly available data." Section 3(2). But how does one peer review *data*, as opposed to the studies that use that data; does this peer review of data require replication of the study itself? Perhaps what is meant by "peer reviewed . . . data" is that the studies reporting on the data have been peer reviewed; but in that case, the court will need to allow for an agency interpretation that deviates from the plain language of the statute. It is also not clear what this "peer review" entails. The legislation could be read to suggest that as long as one "peer" (perhaps even an expert hired by the sponsor of the study under contract) reviews the "data", it meets the requirements of the Act, yet EPA will presumably seek to ensure that these expert reviewers are independent and not contractually controlled by the sponsor of the research. On the other hand, the peer review test – particularly when coupled with the "publicly available" requirement – could be read to imply that published research is the only

science that meets "best available science" requirements, a hurdle that will choke out much of the evidence otherwise available to EPA. Such an interpretation, for example, would eliminate most if not all test data, substantial risk reports, and a variety of other scientifically relevant information that forms the basis for EPA's assessment of the risks of high priority chemicals.

"Best available science" in CSIA also requires that each piece of "science" must "clearly document and communicate risks and uncertainties". But there are a series of National Academies report and a very robust academic literature cited in those reports that offer dozens of different ways to think about this requirement, without any clear convergence in what it means to clearly document and communicate risks and uncertainties. The literature does converge, however, on the reality that such an endeavor is very expensive. Like the first requirement, this second mandatory screen for "best available science" not only subjects EPA to still more potential for litigation given the range of credible interpretations, but threatens a significant, added resource burden on EPA, with no corresponding burden on the manufacturers who produce at least some of this research.

Each of the ambiguous analytical prerequisites in "best available science" creates a new "attachment point" – a credible litigation challenge that can be used strategically by vested interests to delay the program or force EPA into negotiations before, during, or after a rule is published. By and large, these and dozens of other ambiguities in the good science procedures mandated in Senate Bill 1009 are likely to be exploited by some high stakes players. And these high stakes players are likely be comprised of a subset of the chemical industry that produce the least effective and most unsafe chemicals. Whether

the end result is delay or compromise, or a combination of both, the Bill's good science provisions are likely to undercut the ability of EPA to conduct safety assessments, require toxicity testing, and advance chemical regulation.

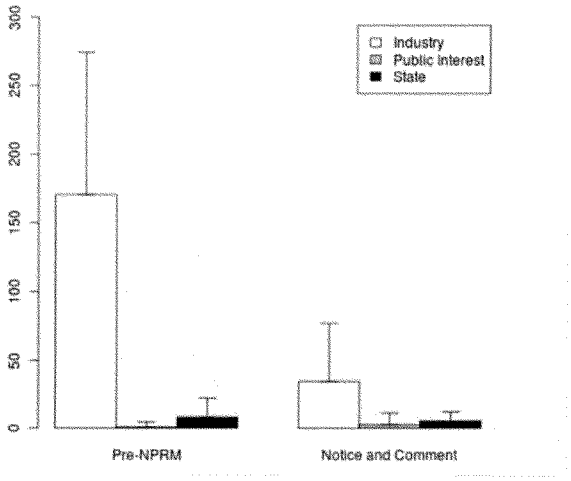
Despite the seemingly high likelihood of added delays from these various good science requirements, however, CSIA does little to anticipate or counteract them. Although there are numerous new requirements and findings required of EPA, only one of these requirements is backed with a legislated deadline. Otherwise, EPA is instructed only to avoid "unreasonable delay," an instruction that will be difficult to enforce in court except in cases of protracted agency inaction. The failure of Senate Bill 1009 to keep EPA's nose to the grindstone stands in stark contrast with other statutes, like the Endangered Species Act, that hold agencies to short, legislative timeframes in implementing the "best available evidence" provisions.

B. EPA will negotiate with high stakes players to avoid some of the delays and resource drains posed by litigation, and these compromises will be largely outside public view

Senate Bill 1009 seems to presume that imposing various legislative constraints on the types of evidence EPA can consider will be sufficient to keep EPA from overstepping in its regulatory role. Yet the literature reveals that precisely the opposite risks are likely from legislation decked with such elaborate, mandatory requirements.

Research in administrative law reveals that a great deal of the agency's decisions can occur outside the formal notice and comment and traditional record-keeping stages of the rulemaking process. In our empirical study of EPA's setting of technology-based standards under the toxic air provisions of the Clean Air Act, for example, there was an unexpectedly high level of communications between EPA and industry before EPA

issued the proposed rule – on average about 80 informal communications (170 total communications) -- per rule.[10] See Bar Chart below. At least some of this interaction can be attributed to EPA's effort to develop a proposed rule that satisfies industry in order to stave off litigation. EPA, in other words, may be compromising at a very early stage in the rulemaking process – one that falls outside the APA notice and comment process – in order to maximize the chances for the survival of its rules. In much more preliminary research on TSCA test rules, we see an even greater amount of industry-exclusive negotiations and discussions recorded in the docket prior to the notice and comment period.



Interest Group Participation in the Section 112 MACT rules of the Clean Air Act, from Wagner, et. al. Rulemaking in the Shade at 124.

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[10] *See generally* Wendy Wagner, Katherine Barnes, and Lisa Peters, *Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Emission Standards*, 63 ADMINISTRATIVE LAW REVIEW 99 (2011); see also Wendy Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L. J. 1321 (2010) (discussing the literature on these pre-NPRM negotiations in the literature more generally).

One tentative lesson that emerges from this research is that EPA (or other agencies for that matter) will negotiate proposed rules with the most litigious groups before publishing a proposed rule. Thus while Congress attempts to add more and more embellishments to the "front door", the back door remains wide open, and elaborate analytical requirements offer little more than window dressing that could actually serve to further obscure this rulemaking reality. As Prof. Elliott observes based on his experience as General Counsel of EPA: "[n]otice-and-comment rulemaking is to public participation as Japanese Kabuki theatre is to human passions – a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues."[11]

Despite the likelihood of these pre-rule negotiations and compromises under the shadow of the dozens of new requirements and procedural hoops imposed by Senate Bill 1009, the bill does nothing to restrict these inevitable interactions, nor does it require EPA to document them. EPA thus appears free to engage in unlimited meetings, telephone calls, and even written correspondence with the highest stakes group to "work out the details" before a proposed rule or interpretation is published – all without logging this information into the record. Senate Bill 1009 also does not require EPA to record its substantial involvement with other federal agencies, including those that will be adversely affected by its rules, or by the influential Office of Regulatory and Information Affairs.

As a result, the "best available science" provisions and other elaborate good science requirements of Bill 1009 are likely to translate, in practice, into a bonanza for

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[11] E. Donald Elliott, *Reinventing Rulemaking*, 41 DUKE L.J. 1490, 1492-93 (1992).

the manufacturers (and their attorneys and trade associations) that make the most unsafe, least effective chemicals. These groups have the highest stakes in the outcome and can be expected to invest the most resources towards threatening litigation and launching other types of time-delaying tactics.

IV. The Bill Does Not Produce Incentives for Better Private Research or The Development of Safer Chemicals; It Should!

The dozens of pages of scientific prescription not only run the risk of unintended adverse consequences, but they ignore the more promising paths for using regulation to encourage manufacturers to do better. There are undoubtedly many ways that Congress could create positive incentives for private research and chemical innovation. I list only a few for purposes of illustration.

A. Creating Positive Incentives for Independent Private Research on Chemical Risks

The best available science provisions in Senate Bill 1009 are directed at the EPA, yet to extent there are documented problems with the quality of the science used by EPA in TSCA, these problems occur much earlier in the scientific pipeline – in the course of producing the research itself. There are scores of books and articles that document problems with sponsored research,[12] yet most of this sponsored research is produced by

[12] *See, e.g.*, SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST (2003); DAVID MICHAELS, DOUBT IS OUR PRODUCT (2008); NAOMI ORESKES & ERIK CONWAY, MERCHANTS OF DOUBT (2009); THOMAS O. MCGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH 233-39 (Harvard University Press 2008).

manufacturers and trade associations, sometimes voluntarily and sometimes not.[13] The literature reveals that some sponsors will contractually control this research by inserting nondisclosure clauses and other mechanisms to control how a study is designed, how the data is collected and analyzed, and how the research is reported.[14] Meta analyses of studies in biomedical medicine reveal statistically significant evidence of a "funding effect", in which research funded by a sponsor produces research outcomes that are much more favorable to that sponsor than research produced independently.[15]

Senate Bill 1009 ignores these well-documented problems with the integrity of private research. While the Bill does require EPA to demand information from submitters about the source of funding for studies (note that the bill is silent on penalties if the submitter refuses to provide this information – the requirements apply only to EPA), information on funding alone tells us very little about the nature of sponsor influence. Under the Bill's approach, the responsible manufacturers are lumped in with manufacturers who strategically manipulate research – the only question asked about private research is who "funded" it, not the much more telling question of whether the sponsor reserved the contractual right to influence the study or researcher.

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[13] Only some of this research is governed by relatively stringent protocols developed by EPA that limit sponsor discretion; other scientific information is informative, but not governed by a predetermined protocol or methods.

[14] See, e.g., David Michaels and Wendy Wagner, *Disclosure in Regulatory Science*, 302 SCIENCE 2073 (2003) (citing this literature).

[15] See, e.g., Justin E. Bekelman, Yan Li, & Cary P. Gross, *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454 (2003).

Biomedical journals require that the researchers disclose the nature of sponsor control.[16] In order to make regulatory research more consistent with scientific standards, the Bipartisan Policy center and the Administrative Conference of the U.S. both recommended that private sponsors should be required to disclose whether they reserved the contractual right to influence the research they sponsor.[17]

Rather than settling for an uninformative disclosure of funding as Senate Bill 1009 requires, Congress should require that the sponsors disclose whether they reserved the right to influence the research they sponsored. Congress should also require that all underlying data that informs regulation be shared with the general public – on a public database. Such a legislative amendment would complement the existing requirements on federally funded research. (A similar proposal has also been endorsed by both ACUS and the Bipartisan Policy Center.) [18] CSIA already notes the importance of publically available data in its definition of "best available science," but the bill does not appear to provide any financial or infrastructure support for a public database.

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[16] See, e.g., ICJME Uniform Requirements for Conflicts of Interest, available at http://www.icmje.org/ethical_4conflicts.html ; ICJME Uniform Requirements for Authorship, available at http://www.icmje.org/ethical_1author.html

[17] *See, e.g.*, BiPartisan Policy Center, Improving the Use of Science in Regulatory Policy 42 (Aug. 2009); ACUS Recommendation 2013-3, available at 78 Fed. Reg. 41,352, 41,357

[18] *See also id.*

B. Providing Incentives for Manufacturers to Produce Safer, More Effective Chemicals.

TSCA and the Senate bill both fail to create meaningful incentives for manufacturers to develop more effective and safer chemicals. Instead, manufacturers need only ensure that their chemicals are better than the very worst on the market.

Rather than focus on the worst, EPA should be required to seek out the best performers and hold all other chemical products to these higher standards.[19] Such an approach follows the forty-year old model set in the pollution control statutes– the technology-based standards –which calibrate the nation's pollution standards to what the best industries are already accomplishing in practice. Such a comparative exercise requires much less information than is currently demanded by TSCA or CSIA to regulate a chemical. EPA would need only to examine the relative toxicity, cost, and effectiveness of chemicals – a full-blown cost-benefit analysis that quantifies every risk and benefit of thousands of chemicals on the market would no longer be required.

Legislation that directs EPA to hold chemical manufacturers to the high standards of their competitors could transform U.S. chemical policy. Such an approach should create powerful incentives for innovation and competition, currently absent in our federal programs; raise product standards that in turn catalyze higher international standards; and lead to more streamlined and expeditious regulation that will better protect the public health and environment. EPA will be liberated from the current approach that forces it to

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[19] This more incentives-approach to chemical regulation is sketched out in Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 INDIANA L. J. 629 (2008) and "Racing to the Top: How Regulation Can be Used to Create Incentives for Industry to Improve Environmental Quality" (forthcoming FSU Journal of Land Use and Environmental Law).

conduct exhaustive cost-benefit analyses on thousands of chemicals only to find it has authority to eliminate only the bottom one-tenth of one percent of toxic chemicals in commerce.

Thank you again for the opportunity to testify on Senate Bill 1009. I look forward to your questions.

Mr. SHIMKUS. Thank you very much.

Now I will recognize myself for 5 minutes for the first round of—or the round of questionings.

And my first question I want to direct to Mr. Dooley, Mr. Rosenberg and I think Mr. Garfield. And it is based upon the question, let me start this, is based upon the question that I asked Mr. Jones. And many witnesses have testified before our committee on the strengths and successes of existing TSCA Section 5 provisions for new chemicals and new uses of existing chemicals.

Are the changes to TSCA Section 5 in the Senate bill needed and why? Cal, if you would start.

Mr. DOOLEY. ACC, you know, supports the provisions of the modifications of Section 5 in CSIA. We recognize that it is important, even with the new chemicals, that you do have provisions that do allow for EPA to make an affirmative determination that the new chemical will likely meet the safety standard, and that we accept that it is an obligation upon the industry and the manufacturer to provide that information and to allow them to make that determination.

Mr. SHIMKUS. Mr. Rosenberg?

Mr. ROSENBERG. EPA—thank you. EPA has asked hundreds of manufacturers for data in the new chemical program since its inception. Without exception, those data have either been provided or the premanufacturer notice was withdrawn. So the deficiencies, if you will, in Section 5, in my view, go to where you end up if you really want to regulate a new chemical, and you end up in Section 6. Section 6 has the least burdensome alternative hurdle, which I completely agree with Jim Jones, is an unmanageable hurdle for the Agency.

So the changes that are made in Section 5 in the bill do one important thing. They do what we are really looking for, which is create a more credible program. And the fact that there is an affirmative determination gives, at least most people, a level of comfort that things haven't just gone through because the deadline expired.

Mr. SHIMKUS. Mr. Garfield?

Mr. GARFIELD. We are still doing some analysis on this, but we are also comfortable with the more—with the creation of a more credible program. The two concerns are ones that have been highlighted before; one, making sure that the timeline and deadlines that have been set are ones that are actually effectuated, and then two, making sure that confidential business information is—continues to be protected.

Mr. SHIMKUS. Do you three feel that this would—has a chance to harm innovation?

Mr. DOOLEY. Well, there is always, you know, that potential if EPA, you know, didn't take any judicious approach, but I would say that with our experience, and is very consistent with what Mr. Rosenberg said, is that EPA's current administration of the new chemicals act has been pretty effective, in that it has resulted in, you know, the U.S. being at the forefront of bringing new chemicals on the market that are being used safely, that are ensuring that we are at the forefront in developing innovations, and that is validated by the number of patents that we receive, the disparity in terms of the number of new chemicals and new innovations

brought into the marketplace in the U.S. versus our competitors in the EU.

And so we also know that, you know, that, you know, that there are going to be some provisions, perhaps even under the Administrative Act, that can give us a recourse if EPA oversteps their bounds, even in the request of some information.

Mr. SHIMKUS. Mr. Rosenberg?

Mr. ROSENBERG. Thank you. The innovation is a delicate thing, and it depends on what kind of market the chemical is going to have, how much volume it will have, as—and how innovative it is, as to what cost you can bear in going through a regulatory program. Any screening program for chemicals that EPA has will put some drag on innovation because some companies or some chemicals won't be able to bear the cost, but this is a good compromise. This is analogous to what happens in other parts of the world. In no part of the world that I am aware of, including Europe, does the Agency have to make an affirmative finding of safety before a new chemical gets to the marketplace. EPA has the strongest power because it is a premanufacturing requirement, not a premarketing requirement. So nothing—there is no economic value of the chemical yet if it hasn't hit the market, whereas in Europe, you can go to the market without—by just filing a piece of paper.

Mr. SHIMKUS. And speaking to innovation, I would not want to leave Mr. Garfield without a chance to respond.

Mr. GARFIELD. I also agree it is a reasonable compromise that will be impacted perhaps more by EPA's practice. So in reality, the way this works, including the deadline, is that when you come up against the deadlines, EPA and a company will negotiate a suspension of that deadline to ensure that the progress continues to be made in resolving the open issues. And so in part, a lot of this will depend on whether EPA stays true to the deadlines that you have offered or whether they do not.

Mr. SHIMKUS. My time has expired. Chair now recognizes Mr. Tonko for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair.

We heard from EPA earlier that cost-benefit analysis should not play a role in the determination of whether a chemical meets the safety standard under a reformed TSCA. The bill before us continues to use the unreasonable risk standard that has historically implied a cost-benefit analysis. A number of stakeholders are on record supporting a safety standard that focuses exclusively on risk, not cost-benefit analysis. For example, ACC's 2009 principle state, and I quote "consideration of the benefits of chemicals being evaluated, the cost of methods to control their risks, and the benefits and costs of alternatives, should be part of EPA's risk management decision making, but should not be part of its safe use determinations." In other words, the determination of whether a chemical meets the safety standard for a particular use should not involve a cost-benefit analysis.

Mr. Dooley, does ACC still support that principle for TSCA reform?

Mr. DOOLEY. Yes, we do. If you had—you know, if you really look at, you know, our policy is, and if you look at the CSIA, is that there is not a requirement to do a cost-benefit analysis on the

prioritization, nor is there a consideration of the cost-benefit analysis in the safety assessment. But when you get to the safety determination, when EPA is making a decision that for some intended use, that there needs to be a restriction, a regulation or perhaps a ban, then we think it is appropriate that you do a cost-benefit analysis of that specific action by EPA, because you might have an instance there where, let us just say it is mercury in a compact fluorescent bulb, you know, something that, you know, an innovation that is, you know, contributing to significant energy savings. That mercury is a critical component of that technology. If you had EPA that would choose to ban mercury because it is potentially a hazardous exposure, and they didn't go through and do a cost-benefit analysis, or are there other alternatives that could contribute to the same environmental benefits and energy efficiency benefits, it would result in bad regulation from our perspective, and bad public policy.

Mr. TONKO. Thank you.

Dr. Denison, do you think that cost-benefit analysis should be kept out of the safety standard in a reformed TSCA?

Mr. DENISON. Yes, I do, Mr. Tonko. I think the—I have a different reading than Mr. Dooley of what the bill requires because I think he stated that the—that cost-benefit analysis should come in at the point of the safety determination. I think the safety determination needs to be a health-based, risk-based determination on the science.

Now, the factors that Mr. Dooley mentions are appropriate to consider in determining how to address a risk for a chemical that fails a safety standard, and the bill needs to make that demarcation quite clear. That is actually how I read ACC's principles back in 2009.

Mr. TONKO. Thank you. And, Mr. Igrejas, does the Safer Chemicals, Healthy Families Coalition have concerns that the unreasonable risk standard in the bill before us will not be a pure health standard?

Mr. IGREJAS. Absolutely. We read the bill as not having effectively separated out the cost benefit from the risk decisions, and also retaining the least burdensome requirement, which is related but separate for bans and phase-outs.

Mr. TONKO. And should any TSCA reform bill this committee considers be absolutely clear that cost-benefit analysis is not a part of the determination that a chemical meets safety standard?

Mt. IGREJAS. We believe it should be.

Mr. TONKO. S. 1009 also leaves in place the substantial evidence standard for judicial review that played a significant role in the asbestos decision.

Ms. Wagner, how common is that heightened standard of review in the environmental law context?

Ms. WAGNER. Typically, the Agency is held to an arbitrary and capricious standard, so it is very unusual.

Mr. TONKO. Will that standard of review make it harder for EPA to prevail in court when it takes action under TSCA than under other environmental statutes?

Ms. WAGNER. It is definitely a higher burden. I think the case law is a little murky. Some courts actually don't seem to use sub-

stantial evidence differently than others, but some do. On balance, it is likely to be a higher burden.

Mr. TONKO. Thank you. There is a strong public interest in improving EPA's ability to take action under TSCA to address the serious risks we face from chemical exposures. We have better working models for dealing with risks and other environmental laws, the pesticides laws, for example. Any TSCA reform bill, in my opinion, considered by this committee should remove the known obstacles to TSCA implementation, such as the cost-benefit analysis component of the safety standard, and this heightened standard of judicial review.

And with that, I believe my time is up and I yield back.

Mr. SHIMKUS. Gentleman yields back his time.

The Chair now recognizes, I believe, Mr. Green from Texas for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

My first series of questions I want to ask, and they are just yes or no, for all witnesses. Briefly, do you believe that Lautenberg-Vitter is an improvement over current law or is status quo preferable?

Mr. Dooley?

Mr. DOOLEY. Yes.

Mr. ROSENBERG. Yes, it is an improvement.

Mr. DENISON. Mr. Green, in some respects yes, in other respects no.

Mr. GREEN. OK. Mr. Garfield?

Mr. GARFIELD. My answer is the same. In some respects yes, in other respects no, but in the respects where it is no, it can be improved.

Mr. GREEN. Mr. Igrejas?

Mr. IGREJAS. I say no.

Ms. WAGNER. With respect to the good science provisions, no.

Mr. GREEN. OK. Well, for all the witnesses, in your opinion, are the issues raised in today's hearings on Lautenberg-Vitter issues that can be improved through clarification, or are they issues that fundamentally cannot be corrected? Why don't I ask the last four since you all are the ones that said it wasn't an improvement?

Mr. DENISON. Congressman, I do believe the problems can be corrected, and that is based on a number of years of dialogue with other stakeholders, including the two gentlemen to my right here. So I think there are solutions at hand if we can get down to the hard work of negotiating this through and finding the right balance.

Mr. GREEN. OK. I guess the reason I asked that to start with is that, you know, we know the law from 1976 is old and we need to update it, but believe me, in a Republican Congress, we are not going to get to where a lot of folks would want to be, but I just want to make sure we move that ball down the field, and that includes passing it through the Senate, because I represent a very urban district in East Harris County that has chemical plants refineries, and people who live along those fence lines. And so that is why I would like to improve the law to the best we can get politically through the House and the Senate.

Mr. Dooley, you—can you explain the—and expand on ACC's views on the EPA's authority to require testing of chemicals? Is it—in particular, does ACC support changes to the EPA's current authority to test existing chemicals, and what changes and why?

Mr. DOOLEY. Yes, we do support, and that is what I think was one of the, you know, the fundamental, you know, positives about this legislation is, for the first time, those, you know, 60,000 or however many grandfathered chemicals will be subject to prioritization and to a safety assessment. And we support those provisions, and—as well as provisions that would give the ability for EPA under new chemicals to have—facilitate their ability to access the data that they need to make a determination whether or not those chemicals do meet the new safety standard.

Mr. GREEN. OK. And I know the ACC's position on the safety standard in both current TSCA and in a modernized TSCA. Is the safety standard in Lautenberg-Vitter identical to the current standard in TSCA?

Mr. DOOLEY. No, it is significantly different in that in the new CSIA—rather, the CSIA——

Mr. GREEN. Um-hum.

Mr. DOOLEY [continuing]. Is that the safety standard of an unreasonable risk to human health and the environment from the exposure to its intended use is the standard there. It does not in any way require a cost-benefit analysis as you do under existing law. So it will make a, you know, significant—it is a significant difference from the existing standard.

Mr. GREEN. And EPA and other areas in environment, do they also conduct cost-benefit analyses?

Mr. DOOLEY. I am not——

Mr. GREEN. OK.

Mr. DOOLEY [continuing]. Sure if I—I need to do a little more research on that one.

Mr. GREEN. And one of the issues is that the Lautenberg-Vitter would—has an addition of deadlines compared to TSCA. Is that a benefit as compared to—a benefit from the additional deadlines?

Mr. DOOLEY. Well, you—the issue of deadlines has been a subject of a lot of conversation with Administrator Jones that was here today. You know, from an ACC perspective, you know, we have no objection to deadlines, but we think the deadlines need to be reasonable. And I thought it was interesting when Administrator Jones was making his statement today, he said he needed deadlines. But the people that we need the information on, what is the appropriate deadlines, is the EPA. You know, we need the information from them in terms of how many chemicals do you think is appropriate of the 60,000 that you want to have go through a prioritization and safety assessment, and perhaps a safety determination. How many of those can you do, and how many FTE's do you need to do, and what is a reasonable time frame to do those.

I think what is difficult for members of Congress in constructing this legislation is to develop arbitrary deadlines that you would think EPA can meet. What the legislation attempts to do is put the onus and the burden on EPA to set deadlines that they are compelled to meet, which would then be informed upon the capacity

and the expertise that they have to carry out the provisions of CSIA.

Mr. GREEN. OK. Mr. Denison, your testimony discussed the process for evaluating new chemicals. How would EPA determine if a chemical is likely safe under this legislation?

Mr. DENISON. Congressman, the details of that are left to EPA, I think, not specified in the legislation in any detail, but I think the key here is that there is first the affirmative requirement that evidence of safety be available on a chemical in order for that chemical to be sold. And second, that the bar is actually intentionally, I think, lower than it is for a chemical that is already on the market. So the difference between likely meets the safety standard and meets the safety standard reflects the fact that that chemical is in an early stage of development, it has not yet been on the market, and, therefore, the amount of information and the amount of ability to demonstrate definitively its safety is appropriately less. But the key difference from current law is, as Mr. Jones stated, changing from a passive system where unless EPA finds a problem, that chemical simply can come onto the market, to one that requires EPA to affirmatively find some evidence of safety as a condition for market entry, and that is a key change.

Mr. GREEN. How does giving EPA the authority to issue orders for testing requirements as found in Lautenberg-Vitter an improvement over the present law?

Mr. DENISON. Congressman, the length of time that EPA has to take to get a rule through to require testing averages about 5 years. An order could be issued within a few months. We think that is a significant improvement. The only problem I would flag here is that, while the bill makes it easier for EPA to get information, it limits the points in time in the process when it could do so. So, for example, if EPA has a new chemical or a chemical that it is trying to prioritize, and it finds it doesn't have enough data, the bill actually strips the current authority EPA would have to require testing at that stage in the process. We think that is a problem.

So there are some positive aspects of the bill in this regard; order authority and the removal of the requirement to first show risk, but there is also some restrictions on EPA's current authority to actually require testing.

Mr. GREEN. Mr. Chairman, I know you have been very kind and—but obviously we need to deal with that as a committee when we—to address that. Thank you.

Mr. SHIMKUS. That is because I have great affection for my colleague from Texas.

So now I would like to recognize my colleague from New Jersey, Mr. Pallone, for as much time as he wants to consume. How about that?

Mr. PALLONE. Well, I won't use too much, I promise, but thank you, Mr. Chairman. I am pleased the committee has convened this hearing, and I certainly appreciate the efforts of my late Senator from New Jersey, Senator Lautenberg, to bring both sides together on this critical issue.

I have met with stakeholders in the environmental community and in the chemical industry, and we can all agree that the status

quo is not working. The GAO has included the current TSCA statute in its high-risk series over the last several years, citing EPA's lack of authority to limit exposure to chemicals that may pose substantial health risks. And I believe there are many other issues that all stakeholders can agree upon, including striking the language that compels the EPA to pursue the least burdensome requirement that is so strict, it prevented EPA from regulating asbestos.

So, Mr. Chairman, I hope to work with you and our colleagues to craft a bipartisan bill. And I just wanted to ask two questions, if I could.

First is posed to Mr. Denison, and that is, you state in your testimony that, and I quote, "by EPA merely designating a chemical as high or low priority, all States would be precluded from imposing a new requirement on the chemical."

So my question is, do you feel this preemption mechanism is triggered too early in the process, and if so, what type of timeline, if any, do you consider practical?

Mr. DENISON. I do, Congressman. I think the extent to which the law will restrict States' ability to act needs to be placed at the end of the process of EPA's evaluation and determination of the safety of a chemical, and where necessary, the promulgation of a rule that applies the appropriate restrictions. If that preemption kicks in earlier in the process, as it does for new requirements under the bill, the concern I have is that States would not be able to act, and then the incentives for dragging out the length of time it would take to get from simply EPA prioritizing a chemical to that final action, the incentives would be to drag that out as long as possible.

So we need a system that provides incentives for efficient and effective action, and I worry that provision in particular would run counter to that.

Mr. PALLONE. Do you want to talk about a time—a different timeline any more than you have, or——

Mr. DENISON. Yes. I think the—those triggers for preemption need to occur at the final action of the Agency. If it finds a chemical meets a safety standard, that would be the final action. If it finds a chemical doesn't meet the safety standard, the final action would be the promulgation of that rule that imposes the appropriate risk management, and that should be the trigger for preemption.

Mr. PALLONE. All right, thank you.

And then my second question, Mr. Chairman, is to Mr. Igrejas. I hope I am pronouncing it.

As we work to reform TSCA, I believe one of the most important issues is protecting vulnerable populations, such as infants and those living near chemical facilities. In New Jersey, as you know, we have a combination of both a large number of chemical facilities and a high population density. So the consequences of insufficient protection are dire. And so I wanted to ask you, you mentioned in your testimony that you think, and I quote, "intent and language do not match up regarding protecting these populations." So what do you suggest to ensure the bill works to protect vulnerable populations such as children and those living near the chemical facilities?

Mr. IGREJAS. Sure. Thank you very much. I think vulnerable populations could be clearly defined first, a definition of what it includes; children, pregnant women, heavily-exposed individuals in communities, and then they should be explicitly required to be included in the safety determination and protected by any risk-management measures. That would play the issue out, so to speak, so that we know the decisions that are made, the measures that are taken are protecting the vulnerable populations.

Mr. PALLONE. OK, but nothing more in terms of specifics at this point, other than the definition or how——

Mr. IGREJAS. The definition and clear language that they are included in not just the assessment phase, which is in the bill now, but in the determinations and risk-management measures.

Mr. PALLONE. OK. All right, that is it, Mr. Chairman. I didn't use my 5 minutes. Thank you.

Mr. SHIMKUS. Well, I thank my colleague. And I was going to ask, because it was very interesting, I appreciate you all being here. Maybe we have gone around, but I think we have fleshed out as much as we can right now, and I am sure we will see some of you through our offices as we continue this process.

Just some final comments. It is really hard for me to believe that the product in the Senate bill is not better than the current law. I mean on the face of it, it—a bill that is—a law that is 37 years old and has not been changed, and has proven to be not effective, something has to be better than nothing. I think that is where there is some commonality in moving forward.

The second thing is, this risk-based issue, there is—I guess my—there is—Cal brought up a good issue about the compact fluorescent bulbs, and what is the environmental benefit or societal benefit of maybe a hazardous chemical that is used in a product that benefits mankind. I am not a climate guy here, everybody knows that, but if you are, you like compact fluorescent bulbs, and there is a—some people would believe there is a great return on—in fact, we had debated that in our Cap and Trade Bill on that very same issue.

So there are issues there. Preemption is going to be a contentious issue, and the—and—but I would like people to start talking to us about deadlines because it seems like, through the three panels, well, at least the second two, deadlines was a consistent theme. And I am—Ms. Wagner, I think your testimony was very intriguing, and I think we are going to look further into your comments and try to flesh out some of that stuff.

I have a unanimous consent request that all members of the subcommittee have 5 days to submit an opening statement for the record. So ordered. I would like to ask unanimous consent to insert letters into the record from the California EPA, Breast Cancer Fund, National Conference of State Legislatures, two from the Environmental Working Group, a letter from 35 Senators and lawyers, from 25 medical professionals, and remind—without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. SHIMKUS. And I would like to remind subcommittee members they have 10 days to submit questions for the record. Without objection, so ordered.

Thank you. With that, we want to thank you for your testimony. Please keep working with us. I think there is some great interest to try to move forward, and hopefully throughout this process we can get through the finish line.

And with that, I will call this hearing adjourned.

[Whereupon, at 1:07 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of the Honorable Fred Upton
Subcommittee on Environment and the Economy
Hearing on "S. 1009, The Chemical Safety Improvement Act"
November 13, 2013

(As Prepared for Delivery)

We welcome our Senate colleagues and commend their bipartisan efforts to modernize regulation of chemicals in commerce.

We are also pleased to welcome the administration's views. We want to work closely with EPA's Office of Chemical Safety and Pollution Prevention as we explore options for legislation that the agency will implement for years to come. We also welcome our stakeholder panel. While each witness has distinct views, your leadership is vital in making further progress possible.

Speaking of leadership, we must acknowledge the vital role of our late colleague, Senator Frank Lautenberg – his dedication, his wisdom, his expertise, and his collaborative spirit. S. 1009, with its impressive array of original cosponsors, reflects the deep respect his colleagues had for him when they had the privilege of working by his side.

An appropriate tribute to Senator Lautenberg and his family would be a bill that becomes law.

But enacting a bill with elements as important and complex as S. 1009 won't be easy, and several questions remain:

- Can we give EPA the right resources and tools to tackle a huge workload sorting out thousands of chemicals?

- Despite the work volume, can we ensure agency decisions are grounded in sound science?

- Can we reassure all Americans that chemicals that touch their lives are safe?

- Can we facilitate one integrated, healthy market for chemical products in the U.S., instead of a patchwork of restrictions?

- Can we protect innovation and still get government officials and health care professionals the information they need to do their jobs?

With questions this tough, we can't expect that all provisions of the legislation will satisfy everyone. But we intend to listen carefully to stakeholders and we will work arm-in-arm with members in both parties who want to work constructively toward a common goal: enacting legislation to modernize chemical regulation.

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FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

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Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Hearing on "S. 1009 the Chemical Safety Improvement Act of 2013"
Subcommittee on Environment and the Economy
November 13, 2013

Today, the Subcommittee considers a proposal introduced in the Senate to reform the Toxic Substances Control Act. While there are some positive elements in this legislation, there are also major deficiencies. I could not support it in its current form.

Four years ago, there was widespread agreement among industry, labor, and nongovernmental organizations that TSCA needs to be reformed.

The EPA Administrator said that TSCA had proven to be "an inadequate tool for providing the protection against chemical risks that the public rightfully expects."

The American Chemistry Council said it wanted to work with "stakeholders, Congress, and the Administration to make reform a reality."

And a coalition of public interest groups said that "[b]y updating TSCA, Congress can create the foundation for a sound and comprehensive chemicals policy that protects public health and the environment, while restoring the luster of safety to U.S. goods in the world market."

When I was Chairman, the Committee put considerable effort into building on this consensus and modernizing TSCA. In 2009 and 2010, we held numerous hearings and convened a robust, bipartisan stakeholder process.

At that time, there was widespread support for the creation of an effective federal program, based on giving EPA the data necessary to understand chemical risks and the ability to regulate chemicals found to be dangerous. There was an understanding that an effective federal program would make preemption unnecessary by addressing the serious risks that have motivated states to take action themselves.

Unfortunately, the legislation we will consider today is radically different in several key respects.

Instead of ensuring that EPA has all of the data it needs, this bill blocks EPA from requiring testing of new chemicals.

Instead of empowering EPA to act to regulate dangerous chemicals, this bill imposes numerous new procedural requirements on the Agency, creating potential for significant litigation delays.

Instead of promoting consumer confidence by increasing transparency, this bill allows chemical companies to conceal information about chemical risks from the public. And instead of protecting state authority, this bill has sweeping preemption provisions.

I cannot support legislation that would undermine the few protections that are in current law or that would preempt successful state efforts to protect the public from exposure to toxic chemicals.

While I cannot support this bill as currently drafted, I continue to be in favor of TSCA reform. I hope the Chairman will engage in a bipartisan effort to draft TSCA reform legislation that both Republicans and Democrats can support.

Consensus between industry and its allies is not consensus, just as consensus among environmental groups is not consensus. I want the Chairman to know that if he wants to sit down and build consensus on legislation among all the stakeholders, I am ready to work with him.

I thank all of the witnesses for being here today and look forward to hearing their testimony.

CALIFORNIA
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MATTHEW RODRIQUEZ
SECRETARY FOR
ENVIRONMENTAL PROTECTION

EDMUND G. BROWN JR.
GOVERNOR

June 25, 2013

The Honorable Dianne Feinstein
United States Senate
331 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Barbara Boxer
United States Senate
112 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Kirsten Gillibrand
United States Senate
478 Russell Senate Office Building
Washington, D.C. 20510

RE: S. 1009, Chemical Safety Improvement Act (CSIA) – Concern with Preemption Language

Dear Senators Feinstein, Boxer, and Gillibrand:

I am writing on behalf of the California Environmental Protection Agency (Cal/EPA) to express serious concern about the effects of S. 1009 on California's ability to protect its residents from toxic chemicals, air pollution, and threats to drinking water. You have previously received letters from the California Department of Toxic Substance Control and the California Attorney General's Office expressing reservations about this proposed legislation. (See attached letters of May 31 and June 11, 2013.) We agree with the concerns stated in these letters and write separately to note that as currently written, S. 1009 also could jeopardize California's ability to control greenhouse gases and thereby meet the State's targets under AB 32, the California Global Warming Solutions Act of 2006. Although the Toxic Substances Control Act (TSCA) is clearly in need of reform, we respectfully request that S. 1009 should not be adopted unless amended prior to moving forward in the Senate to address major concerns with the legislation, including the provisions governing preemption of state laws.

The existing and more reasonable preemption provisions currently in TSCA have allowed California to take necessary action over the past three decades to reduce toxic chemicals and protect public health and the environment. Many of our regulatory actions have resulted in beneficial changes in product composition and chemical use that extend far beyond the borders of our state. As an example, California's Safe Drinking Water and Toxic Enforcement

Act (Proposition 65) stimulated nationwide reformulation of numerous products to remove chemicals known to the State of California to cause cancer or reproductive harm. Successes under this law include removing lead from water faucets, eliminating trichloroethylene (TCE) from liquid correction fluid, and more recently removing flame retardants from infant nap mats.

California laws or regulations have also provided a model that is followed in other states or nationally. For instance, California legislation, adopted in 2007 to ban certain phthalates in toys and children's products [Cal. Health & Saf. Code, §§ 108935-108939, Stats. 2007, c. 672, A.B. 1108], was the inspiration for Senator Feinstein's legislation, S. 2663, banning these same chemicals nationally in the Consumer Product Safety Improvement Act of 2008.

After consulting with scientific and legal experts who work for the boards and departments within Cal/EPA, we have identified dozens of California laws and regulations that may be at risk of preemption under the current provisions of S. 1009. Information concerning each of these laws and regulations could be provided at your request, and several examples are highlighted here:

- Global Warming Solutions Act of 2006 (AB 32): Some very potent greenhouse gases, such as sulfur hexafluoride and methane, are of relatively low toxicity. If the EPA Administrator designates any of these chemicals as "Low Priority" under S. 1109, states will be barred from any "prohibition or restriction on the manufacture, processing, distribution . . . or use" of these chemicals. This provision could bar state actions to regulate or control potent greenhouse gases and could undermine California's efforts to achieve our reduction targets under AB 32.

- Reducing Ozone Pollution: California contains major geographic areas in "Extreme" ozone non-attainment. Ozone is a Criteria Air Pollutant that causes or contributes to respiratory disease, asthma, emergency room visits, hospitalizations, and premature death. Nonattainment areas are required to take aggressive action to reduce ozone pollution, including reducing the emissions of ozone precursors such as volatile organic compounds (VOCs). S. 1009 sec. 15, subsection (c) states that the preemption does not apply to a state regulation that is "... adopted under a law of the State . . . related to . . . air quality . . . that (A) does not impose a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance." The California Air Resources Board, however, has a number of regulations that would not be able to take advantage of the exception in subsection (c) because they impose restrictions on the "use" or "distribution in commerce" of specific VOCs in products. This could significantly impair California's efforts to come into attainment with the Clean Air Act and could put millions of people in the Los Angeles area and San Joaquin Valley of California at increased risk of respiratory disease.

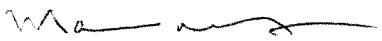
- Drinking Water Safety: More than 60 California water systems contain hexavalent chromium or perchlorate. It is reasonably likely that these will be designated as "High Priority" chemicals under S. 1009, thereby immediately preempting all future state actions, and retroactively preempting existing state laws and regulations once U.S. EPA has acted. This puts future California activities to protect sources of drinking water in immediate jeopardy, and also may endanger historic regulations, including our 1989 ban on the use of hexavalent chromium in cooling towers; our 2007 strict performance and emissions requirements for the chrome plating industry; and the Perchlorate Best Management Practices regulations of 2006.

- Consumer Product Safety: Numerous California laws and regulations have collectively worked to increase the safety of consumer goods and reduce the use of toxic chemicals in products. Specific examples include the 2006 ban on certain flame retardants, which has been replicated or expanded in at least a dozen states; bans on mercury in products ranging from thermostats to thermometers, which are now in place in more than 20 states; a phase-out by 2014 of toxic substances including copper, cadmium, hexavalent chromium, lead, mercury and asbestos in automobile brake pads; and a ban on toxic chemicals in art supplies for young school children. The California Safer Consumer Products regulations, slated for release next month, will constitute the most ambitious effort to date to systematically address the issue of toxic chemicals in consumer products by promoting innovation in safer alternatives and green chemistry. Depending on the scope and interpretation of S. 1009 and the resulting actions of the EPA Administrator, components of the above laws and regulations will be put at risk.

In addition to the above issues, we are concerned that the lack of clarity of some of the preemption provisions in S. 1009 would open the door to extensive litigation. For example, the preemption of state actions that prohibit or restrict "the manufacture, processing, distribution in commerce or use of a chemical substance" in §15(a) and (b) should not be understood to limit states from requiring that information be provided to the public; however we recognize that the ambiguity of the language could cause others to claim that a label or warning to consumers is an indirect "restriction on the . . . distribution . . . or use". This issue requires clarification.

I am confident that this legislation is not intended to invalidate or undermine existing California laws and regulations governing public health and the environment, nor is it the intent to block future innovation and health protection at the state level. Accordingly, we respectfully request that you reconsider the provisions of S. 1009 to ensure that it is written in a manner that will be successful in protecting the public from toxic chemicals, in a reasonably expeditious manner, without unintentionally restricting the ability of states to protect consumers, health, and the environment.

Sincerely,



Matthew Rodriquez
Secretary for Environmental Protection

Attachments

cc: See next page.

cc: Ms. Katie Wheeler Mathews
Deputy Director
Washington D.C. Office of California Governor Edmund G Brown, Jr.

Mr. Cliff Rechtschaffen
Senior Advisor
Office of California Governor Edmund G. Brown Jr.

Brian Nelson
Special Assistant Attorney General
California Department of Justice

Sally Magnani
Senior Assistant Attorney General
California Department of Justice

Ms. Debbie Raphael, Director
California Department of Toxic Substances Control

Mr. Richard Corey
Executive Officer
California Air Resources Board

Mr. George Alexeeff, Director
California Office of Environmental Health Hazard Assessment

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Edmund G. Brown Jr.
Governor

May 31, 2013

Felix S. Yeung, Esq.
Legislative Assistant
Office of Senator Dianne Feinstein
Felix_Yeung@feinstein.senate.gov

Dear Mr. Yeung:

I am writing to you to convey initial comments from the California Department of Toxic Substances Control (DTSC) regarding the proposed Chemical Safety Improvement Act ("the Act"). DTSC is extremely concerned about this bill. DTSC recognizes that the Act includes some positive reforms to the Toxic Substances Control Act ("TSCA"), but at this point, the areas of concern overshadow these improvements. While most of DTSC's concerns center around the Act's preemption provisions, DTSC also has broader concerns regarding the functionality and effectiveness of the Act.

Areas of concern:

- **The expansion of the preemptive effect of EPA action under TSCA.**
    - The Act would broaden vastly the scope and conditions of preemption by TSCA of state and local chemical regulations.
    - There is a need for clarification regarding what constitutes a "prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance," in order to clearly define what types of state actions are intended to be preempted under the Act.
        - Industry may argue that a labeling requirement could be considered a restriction on the use of a chemical substance, which is far too broad an interpretation of this phrase.
    - States would be barred from enforcing existing chemical regulations after issuance of a safety determination by US EPA, even when state regulations are consistent with the findings of US EPA's safety determinations.
        - States should be allowed to continue to enforce their regulations until the Administrator for US EPA promulgates a rule establishing necessary restrictions after making a determination.
    - States would be barred from imposing new prohibitions or restrictions on chemical substances that are identified as "high-priority" as of the time the

Administrator of US EPA publishes a schedule for conducting a safety assessment, not as of the time that such a determination is actually made.
    - States should not be barred from imposing regulations on chemical substances for which they have already evaluated the safety and determined that prohibitions or restrictions are necessary to protect public health or the environment merely because the Administrator has released a schedule by which US EPA will conduct its own assessment.
  - The criteria for a state waiver are nearly impossible to meet.
    - The requirement that "compelling State or local conditions" warrant the waiver is unreasonable, as the risks presented by exposure to chemical substances are unlikely to present localized risks.
- **The safety standard to be used in making safety determinations**
  - There is a need for clarification of the definition of "unreasonable risk of harm to human health or the environment," which is central to the regulatory standard of US EPA's safety determination.
- **The lack of deadlines for US EPA actions both in making the initial determinations of high-priority and low-priority chemicals, and in acting upon unreasonable risks that are identified**
  - Proposed language only says that the US EPA Administrator "shall make every effort to complete the prioritization of all active substances in a timely manner."
    - There is conflicting language in Section 4, subparagraph (e)(3)(E)(i) and (ii) under "Identification of High-Priority Substances." These provisions state that the Administrator both "shall" and "may" identify a chemical substance that has the potential for high hazard or exposure as a high-priority substance.
  - Deferring safety determinations until after receipt of additional test data and information may allow the chemical industry to actively stall the assessment process if no deadline is included.
  - There is no proposed deadline by which the US EPA Administrator must promulgate a rule establishing necessary restrictions after making a determination that a chemical substance does not meet the safety standard under current intended conditions of use.

Background:
The Act first requires US EPA to identify all active chemicals, which are those in use in non-exempted products in the last 5 years. These chemicals will represent US EPA's initial list of chemicals, and EPA will then consider existing information, and where more is needed, will solicit this information from the public. EPA is then charged with conducting a prioritization screening of these chemicals. This screening designates chemicals as either low-priority, when they are "likely to meet the safety standard," or high-priority, indicating that they present a high hazard and exposure or high hazard or high exposure. EPA can also prioritize chemicals that lack sufficient information as high-priority.

Once prioritized, the Administrator of US EPA will publish a schedule for the completion of a safety assessment of high-priority chemicals on a chemical-by-chemical basis. The assessments will result in a safety determination by the Administrator as to whether a chemical substance meets the safety standard under the intended conditions of use. The safety standard is defined as "a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance." If there is a determination that there is insufficient information to make this determination, the Administrator may obtain new data by request, rule, testing consent agreement, or order.

If a chemical does not meet the safety standard under current intended conditions of use, the Administrator may impose, by rule, necessary restrictions or prohibitions on use of the chemical, or a ban or phase-out of the chemical. The latter must be based on a cost-benefit analysis.

The Act significantly changes the preemption provisions in TSCA (currently found in section 18). Under TSCA, a state may apply to the Administrator for an exemption from preemption for a state requirement

> "designed to protect against a risk of injury to health or the environment associated with a chemical substance, mixture, or article containing a chemical substance or mixture if (1) compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under [TSCA], and (2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under [TSCA] and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce."

Under the proposed Act, however, States are preempted from enforcing existing requirements, or establishing new requirements, once the Administrator has issued a completed safety determination for a chemical substance, or published a schedule for conducting a safety assessment of a chemical identified as high-priority, respectively. The preemption provision would apply to State requirements that represent "a prohibition or restriction on the manufacture, processing, or distribution in commerce or use of a chemical substance…", as well as certain requirements for the development or test data or information that would produce information similar to that required under section 4, 5, or 6 of the Act.

The Act does include a section on state waivers from the preemption provisions, but the criteria to qualify for such a waiver make obtaining one nearly impossible. The Act provides that if the State "determines in cannot wait until the end of the period specified in the established schedule and deadline for the completion of a full safety assessment and determination," the Administrator may provide a waiver from the preemption provisions upon a determination that:

> "(i) compelling State or local conditions warrant granting the waiver to protect human health or the environment;
> (ii) compliance with the proposed requirement of the State or political subdivision of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
> (iii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(iv) the proposed requirement of the State or political subdivision of the State is based on the best available science and is supported by the weight of the evidence; or

(2)(A) the Administrator finds a safety assessment or determination has been unreasonably delayed; and

(B) the State certifies that—

(i) the State has a compelling local interest to protect human health or the environment;

(ii) compliance with the proposed requirement of the State does not unduly burden interstate and foreign commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(iii) compliance with the proposed requirement would not cause a violation of any applicable Federal law, rule, or order; and

(iv) the proposed requirement is grounded in reasonable scientific concern."

DTSC is very concerned that the bar has been set too high for obtaining state waivers from the expanded preemption provisions in the Act. The preemption provisions would potentially impact the ability of DTSC to implement certain regulatory responses under the Safer Consumer Products regulations, including product information for consumers, use restrictions on chemicals and consumer products, product sales prohibitions, engineered safety measures or administrative controls, end-of-life management requirements, and advancement of green chemistry and green engineering.

Thank you very much for reaching out to DTSC and allowing us the opportunity to provide input on these important issues.

If you have any questions, please feel free to contact me at (916) 324-7663 or Joshua.Tooker@dtsc.ca.gov

Sincerely,

Josh Tooker
Deputy Director for Legislation
Department of Toxic Substances Control

KAMALA D. HARRIS
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June 11, 2013

The Honorable Barbara Boxer
Chairwoman, Senate Environment
and Public Works Committee
112 Hart Senate Office Building
Washington, D.C. 20510

RE: Concerns with Preemption Language in Chemical Safety Improvement Act, S.1009

Dear Senator Boxer:

I write to convey the concerns of the California Attorney General regarding the proposed Chemical Safety Improvement Act, S.1009. Although we recognize that the Toxic Substances Control Act (TSCA) is in need of substantial reform, we believe that S.1009, as currently drafted, cripples the police powers that California relies on to protect public health and the environment and, in addition, severely compromises California's authority to supplement and complement federal efforts to regulate the safety of chemicals. As a leader in chemical safety and consumer protection, California has a direct stake in the outcome of any reform of TSCA. We respectfully request that S.1009 be amended to address the problems outlined below.

California's Role in Protecting Public Health

California has been a leader in enacting laws that protect public health and the environment, and has served as a laboratory for innovation for other states and the federal government. Many of the innovative laws that California has enacted are jeopardized by S. 1009.

Green Chemistry

Over the past several years, California has undertaken to implement ground-breaking "green chemistry" programs, reflecting an approach to environmental and public health protection that focuses on reducing or eliminating the use and generation of hazardous substances. Green chemistry marks a sharp departure from managing hazardous substances after they already have entered consumer products and our environment. In 2005, the State enacted the California Safe Cosmetics Act, becoming the first state in the nation to regulate toxic ingredients in cosmetics. The next year, California established the California Environmental Contaminant Biomonitoring Program to identify toxics accumulating in California residents and, in 2007, banned plasticizers called phthalates in children's products. In 2008, California enacted

two bills that together created the State's comprehensive Green Chemistry Program. Under that program, the Department of Toxic Substances Control (DTSC) is in the final stages of promulgating regulations that will establish a process for identifying chemicals of concern in consumer products and their potential alternatives, in order to determine how best to limit exposure or to reduce hazard levels.

Proposition 65

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), was enacted as a ballot initiative in November 1986 by 63% of the voters. Proposition 65 was designed to protect California citizens and drinking water sources from chemicals known to cause cancer, and birth defects or other reproductive harm. Proposition 65 requires the Governor to publish, at least annually, a list of chemicals known to the State to cause cancer or reproductive toxicity. Businesses may not discharge these chemicals to sources of drinking water and must warn individuals about exposures to the listed chemicals. The Attorney General is the only official with statewide authority to enforce Proposition 65, and actions by the Attorney General in the name of the People are brought under the sovereign authority of the State.

Using this authority, the Attorney General's Office has taken a number of steps over the years to protect public health, including:

- Required manufacturers to reformulate the "Brazilian Blowout" hair straightener which contained high levels of formaldehyde that sickened hair stylists and their customers, and to provide warnings and accurate labeling of such products.

- Required manufacturers, sellers, and distributors of vinyl "jump houses" for children, to lower the levels of lead in the vinyl. Children playing in the jump houses were previously exposed to significant levels of lead from the vinyl.

- Required terminal operators at the Los Angeles and Long Beach Ports to provide a strong warning program about diesel fumes emitted into surrounding neighborhoods, and to implement a Clean Trucks Program to reduce diesel emissions from Port operations.

- Required manufacturers to reduce the lead in calcium supplements, multi-vitamins, and other nutritional supplements, including prenatal supplements, supplements for women of childbearing age, and supplements for children to levels below where Proposition 65 requires point-of-sale warnings, an area in which the Federal government has not taken regulatory action.

- Required manufacturers of wooden playground structures to stop using wood treated with chromated copper arsenate, which exposed children to high levels of arsenic.

- Required manufacturers of Mexican chili candies to reduce the high lead levels in their candies by improving their manufacturing processes, including washing the chilies before manufacture. The candies are eaten extensively by children in the Mexican-American community in California.

California's Programs are Threatened by S.1009's Overreaching Preemption Provisions

States Must Not Be Preempted in the Absence of Federal Regulation

Among the bedrock powers reserved to the states under the Tenth Amendment to the U.S. Constitution is the exercise of police powers to protect the health and safety. The courts have long recognized that regulation of health and safety matters is historically a matter of significant state concern, and the federal government has traditionally granted the states great latitude to protect the health and welfare of their citizens. To take away those historical police powers through preemption in instances where the federal government has yet to regulate or will not be regulating a chemical substance serves only to increase the risk to public health. Under S.1009:

- States are prohibited from enforcing existing state laws or from adopting new laws regulating chemical substances determined by U.S. EPA to be "high priority" even before federal regulations or orders become effective, creating a period of months or potentially years where such chemical substances are unregulated. See S.1009, § 15(a)(2).

- States are barred from adopting and enforcing new laws regulating "low priority" chemical substances – of which there will be tens of thousands – even though the U.S. EPA Administrator is also expressly prohibited from regulating those substances and has made only a preliminary safety assessment that is immune from judicial review. This creates a gaping and permanent regulatory vacuum. See S.1009, §§ 4(e)(3)(H)(ii), 4(e)(5) and 15(b)(2).

States Must Retain the Ability to Ban Use of a Chemical Substance In-State

Even where the federal government has acted to regulate a chemical substance, states must retain the ability to ban the use of that chemical substance in-state, in order to protect its residents' health and safety. In-state use bans – which do not prohibit the manufacture or processing of the chemical substance for export – do not unduly burden interstate commerce.

- Existing law gives states authority to prohibit the use of a chemical substance in-state without having to apply to the U.S. EPA for a waiver. See 15 U.S.C. § 2617(a)(2)(B)(iii). S.1009 revokes this authority by preempting state prohibitions or restrictions on the use of a chemical substance. See S.1009, §§ 15(a)(2), 15(b)(1) and 15(b)(2).

States Play a Vital Role as Co-Enforcers of Federal Standards

In numerous areas of environmental law, states and their political subdivisions play a vital role in enforcing federal standards. For example, under the nation's solid hazardous waste law – the Resource Conservation and Recovery Act (RCRA) – once state programs are certified by the federal government, states assume primary responsibility for enforcement. With respect to consumer product safety, federal law provides states with the ability to enforce federal regulations and orders. Under existing TSCA provisions, states are allowed to enact requirements that are "identical to the requirement prescribed by the Administrator," gaining the ability to enforce that requirement without having to apply for a waiver.

- S.1009 provides none of the above avenues for state enforcement. Rather, enforcement of all new prohibitions or restrictions on chemical substances is wholly dependent on the resources, priorities, and discretion of the U.S. EPA and the U.S. Department of Justice.

States Should Have a Reasonable Opportunity to Obtain a Waiver to Enforce a Higher Degree of Protection Within Their Borders

Under the existing provisions of TSCA, where the Administrator has adopted a rule with respect to a chemical substance, states are allowed to apply for an exemption to provide a higher degree of protection, so long as state requirements do not make it impossible to also comply with federal law (i.e., create a conflict) or unduly burden interstate commerce. See, e.g., 15 U.S.C. 2617(b).

- S.1009 has no directly analogous provision. The bill allows states to apply for a waiver to enforce a prohibition or restriction, if the application is filed prior to the Administrator's completion of a safety assessment/safety determination. But, depending on the timing of the state's application, the waiver either terminates automatically after completion of the safety assessment/safety determination or terminates if it "conflicts" with the Administrator's safety assessment/safety determination (which itself is not a restriction or prohibition). See S.1009, § 15(c)(6).

- Even then, S.1009 sets up an unrealistic test if a state seeks to obtain a waiver to adopt and enforce its requirements. Specifically, a state must certify that "the State has a compelling local interest to protect human health or the environment." See S. 1009, §§ 15(d)(1)(B)(i) and 15(d)(2)(B)(ii). It is unclear what is meant by "local interests" or what showing would be required. It is likely not possible to show unique circumstances that differentiate health risks by geography, since dangerous chemicals don't act differently in different locations. Risks from exposure to chemicals in the home, at the office or at retail establishments do not vary from one state to the next. Under this standard, it is unclear whether a waiver could ever be granted.

Thank you for your consideration of our comments. Please feel free to contact me if you have any questions or need further information.

Sincerely,

Brian Nelson (SM)

BRIAN NELSON
Special Assistant Attorney General

For KAMALA D. HARRIS
Attorney General

cc: The Honorable Diane Feinstein

November 13, 2013

The Honorable John Shimkus
Chair, Subcommittee on Environment and the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Paul Tonko
Ranking Member, Subcommittee on Environment and the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Re: "S. 1009, Chemical Safety Improvement Act" Hearing

Dear Chairman Shimkus and Ranking Member Tonko,

Thank you for holding this important hearing on "S. 1009 -- the Chemical Safety Improvement Act." I very much appreciated the opportunity to testify at the Subcommittee's June 13 hearing entitled "Title I of the Toxic Substances Control Act: Understanding its History and Reviewing its Impact," and hope that the information I provided at that time was useful to the Subcommittee's work. That hearing provided an important opportunity to discuss the failings of the Toxic Substances Control Act (TSCA), but it was not directly focused on the recently introduce Senate bill, the Chemical Safety Improvement Act (CSIA). On behalf of the Breast Cancer Fund, I would like to take this opportunity to express our deep concerns with the CSIA.

The Breast Cancer Fund is the only national organization focused solely on preventing breast cancer. We do that by working to eliminate our exposures to toxic chemicals and radiation linked to the disease. Reform of the outdated and ineffective Toxic Substances Control Act has long been a priority of our organization. For the last four years, the Breast Cancer Fund has served on the Steering Committee of Safer Chemicals, Healthy Families, a coalition of over 450 organizations working to reform TSCA, including health professionals, health affected groups, environmental justice organizations, environmental groups and businesses.

The Chemical Safety Improvement Act Falls Short

The introduction of S. 1009, the Chemical Safety Improvement Act (CSIA), has changed the conversation in Washington, DC. No longer are we talking about "if" we should reform the broken chemicals management system set up by the 37-year-old Toxic Substances Control Act (TSCA). Now we are engaged in a conversation about what that reform must look like to be meaningful and truly safeguard the American public, and particularly vulnerable populations, from exposures to dangerous chemicals. The Breast Cancer Fund greatly appreciates this shift, and is eager to work with policy makers and stakeholders of every perspective to make meaningful reform a reality for our nation and our children.

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Protecting public health and the environment should be the primary and overriding goal of TSCA reform. Unfortunately, the CSIA falls short of that goal. As written, this legislation could set back the few current protections in place, particularly at the state level, without ensuring that the Environmental Protection Agency (EPA) has the necessary authority, tools and resources to provide real federal protection. While the Breast Cancer Fund opposes the bill as it is currently written, we stand ready to work with Congress and all stakeholders to address the bill's significant flaws and craft meaningful and effective chemical policy reform.

To be true reform and to accomplish the goal of protecting America's families and workers, any effective chemicals management system must include the following elements. Unfortunately the CSIA as currently written fails to meet these basic requirements.

A safety standard that is health-protective, particularly of vulnerable populations.
The safety standard must explicitly protect vulnerable populations. Pregnant women, children, workers, and communities around areas of high chemical exposures all need and deserve our protection; and by protecting them, we will protect not only ourselves, but future generations as well.

The CSIA does not explicitly require a consideration of the health impacts of chemical exposure to our most vulnerable populations including pregnant mothers, children, workers or disproportionately exposed communities. The legislation also maintains the current TSCA safety standard that has failed to protect public health. This continued use of TSCA's flawed "unreasonable risk of harm to health or the environment" safety standard raises a number of unsettling questions: Who decides if a chemical presents an "unreasonable risk?" And who bears the burden of proof for meeting that standard – the EPA (and therefore the public) or industry? One of the major failures of the current TSCA is that the burden falls on the EPA to prove chemicals are not safe rather than on industry to demonstrate their chemicals are safe. Any meaningful reform of TSCA must clearly shift the burden of proof to industry to demonstrate the safety of the chemicals they manufacture and market.

Finally, we are not exposed to one chemical at a time, or even just one source of a particular chemical. It is essential for the EPA to consider aggregate exposures when determining safe exposure levels. The CSIA allows for such consideration but does not require it.

Use of the best science available. TSCA reform should ensure the use of the best available science by incorporating recommendations from the National Academy of Sciences on reforming the EPA's risk assessment process. Legislation must also protect the integrity of scientific review from undue industry influence and incorporate science from all sources, including government agencies and academia.

For years, the chemical industry has been waging a well-funded campaign against government and academic science that shows adverse health effects and increased health risks associated with specific chemicals. The language in the CSIA reflects those chemical industry efforts to

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undermine and devalue government and independent science while protecting industry-funded science. To ensure the highest quality and best available science, the CSIA should require scientific procedures and guidelines developed in the bill follow the recommendations of the National Academy of Sciences for 21st century toxicology.

Require data on all chemicals. The EPA should require chemical manufacturers to demonstrate via scientific data that a particular chemical is safe. The absence of data should not default to assuming the chemical is safe.

The CSIA sets up a two-tiered system for EPA review of the safety of industrial chemicals. Chemicals designated as high priority must be scheduled for a safety assessment and safety determination. Low priority chemicals are those that the EPA determines are "likely to meet the safety standard," and once so designated, they are set aside with no further action unless the EPA is explicitly requested to reevaluate the low priority designation of a specific chemical. Under the CSIA, there is no upfront requirement for manufacturers to develop or submit scientific data showing a chemical is likely to meet the safety standard of not presenting an "unreasonable risk of harm to health or the environment." In fact, the burden falls to the EPA to find information that is "reasonably available to the Administrator" including requiring the EPA to actively search for publicly available data. The EPA can request or require more data, by consent agreement or order, but this adds an addition level of administrative burden, a burden that should be required of the industry that stands to benefit from the beginning. The bill should make clear that no chemical will be designated as low priority without sufficient data to affirmatively show it is safe.

Action on the worst chemicals. For some chemicals we already have enough scientific evidence showing harm to be able to take action now to reduce unsafe exposures. TSCA reform must allow the EPA to take fast action on the worst chemicals, including persistent, bioaccumuative toxins (PBTs): toxic chemicals that break down extremely slowly in the environment, often over the course of decades, and accumulate in the tissues of organisms, including humans.

Instead of allowing for fast action on the worst chemicals, the CSIA retains TSCA's impossibly high regulatory burden when the EPA identifies the need to ban or phase out a toxic chemical. Since these actions would be reserved for the most dangerous chemicals, this provision would have the exact opposite effect of what is needed – creating regulatory barriers that will slow down needed restrictions, or even halt them altogether, rather than expediting action on the worst chemicals.

Include sufficient deadlines and timetables. Enforceable deadlines are essential, particularly given the history of the chemical industry's ability under current TSCA process to delay evaluation and regulation of chemicals for years and sometimes decades. The CSIA provides virtually no deadlines or timelines for completing critical tasks such as safety assessments and safety determinations. While there are a few deadlines for creating procedural guidelines, language like "promptly," "every effort to complete…in a timely manner," "from time to time,"

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"expeditiously completing," "reasonable extensions," "reasonable period," and "as soon as possible" take the place of specified timetables and deadlines. In our criminal justice system there is an expression that "justice delayed is justice denied." In this case, chemical regulation delayed allows for the continuation of dangerous exposures that threaten public health.

Protecting the public's right to know about the health hazards of specific chemicals. Reform should require that the public have access to information regarding the safety of chemicals, including the identity of hazardous chemicals. State and local agencies also need chemical identity and safety data to allow them to do their job of protecting citizens from hazardous exposures.

The CSIA does not go far enough to ensure the public has adequate access to information on the safety of the industrial chemicals that end up in their environment, workplaces, communities and consumer products. The bill would allow the EPA to share confidential business information ("CBI") with state and local authorities and medical personnel with certain conditions, which is a step forward. However, the process for sharing the information in most cases calls for a 15 to 30 day delay after alerting the submitter of the CBI claim before releasing the data; and provides the opportunity for judicial review, allowing the submitter to sue to keep the information confidential. These judicial reviews could prevent the sharing of the information or at the very least cause significant delays.

Currently, the EPA has little authority and even fewer resources to challenge CBI designations, so the vast majority of claims are simply accepted without any serious review of their legitimacy. Knowledge of the chemical identity, particularly of a hazardous substance, is critically important for manufacturers to make safer choices for their products, for workers to protect themselves and their families from unsafe exposures, for retailers crafting policies to protect their customers, for scientists to conduct effective research and ultimately for consumers wanting to make informed purchases to protect their families. Given the historic and ongoing abuse of CBI, it is particularly troubling that the CSIA leaves all current CBI claims in place, grandfathering them in with no requirement or incentive for the EPA to review or substantiate the need for that information to be held as confidential.

Allow the states to continue to protect their citizens. Finally, TSCA reform must respect the right of states to protect their residents if the federal government fails to do so or is slow to act. With the EPA's hands tied by the complete failure of TCSA, citizen demand has driven states from around the country to step up to provide protection from harmful chemical exposures through legislation on a variety of chemicals and uses. These laws not only protect citizens within the state borders, but have also had a positive impact on manufacturing practices and products throughout the country. States must continue to have that ability.

The CSIA does not adequately protect the right of states to safeguard their citizens from harmful exposures when the federal government can't or won't take action. Instead, it could roll back the current state protections in place and would stifle future state protections. State laws that are in

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place when the CSIA is enacted would be preempted once the EPA has completed a safety determination of the particular chemical in question. However, completion of the safety determination is not the same as having federal safety protections in place. The process and timeframe between issuing a safety determination and issuing of a final rule to implement needed restrictions can be a very long one, including the protracted process of rulemaking and the possibility of lawsuits that could delay implementation indefinitely.

Under the CSIA, states would be barred from passing future laws once a chemical is designated as low priority or designated as high priority and scheduled for a safety assessment and determination. Given the lack of deadlines in the bill, once scheduled, a chemical could sit for any number of years before action is taken, during which time the state's hands are tied and the public unprotected. Once a chemical is designated as low priority, which is designed to be basically an educated guess by the EPA as to whether or not a chemical will meet the safety standard, the states are also prohibited from taking any action on that chemical.

Chemical policy reform is a public health necessity and it is urgent and essential that we create a chemicals management system that protects all of us, including the most vulnerable among us. Congress has a moral imperative to pass legislation strengthening the way chemicals are regulated to provide the public real protection from dangerous chemicals. For the reasons outlined in this letter, the Breast Cancer Fund opposes the CSIA in its current form. We are committed to working with the committees in both the House and the Senate to make the changes necessary to create a bill to reform TSCA that is truly health protective.

Thank you again for holding this important hearing. We look forward to working with both the House Subcommittee on Environment and the Economy, and the full Energy and Commerce Committee, to craft and adopt a bill that reforms TSCA in a truly health-protective manner.

Sincerely,

Jeanne Rizzo

Jeanne Rizzo, R.N.
President and CEO
Breast Cancer Fund

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The Forum for America's Ideas

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New Hampshire House
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Patsy Spaw
Secretary of the Texas Senate
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William Pound
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July 24, 2013

The Honorable Barbara Boxer
Chairman
Environment and Public Works Committee
United States Senate
112 Hart Senate Office Building
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The Honorable David Vitter
Ranking Member
Environment and Public Works Committee
United States Senate
516 Hart Senate Office Building
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Re: S. 1009, "The Chemical Safety Improvement Act"

Dear Chairman Boxer and Senator Vitter:

On behalf of the National Conference of State Legislatures (NCSL), we applaud the decision by the Environment and Public Works Committee to convene a hearing aimed at understanding and examining issues surrounding the history and impact of the Toxic Substances Control Act (TSCA). While efforts such as these will serve as key components to update the statute to reflect advances in science and technology to better evaluate and regulate chemicals, we write today to also express serious concerns with current TSCA reform legislation, S.1009, "The Chemical Safety Improvement Act."

NCSL encourages Congress to reform and modernize TSCA and appreciates the attempt of this legislation to include elements outlined in NCSL's Federal Chemical Policy Reform Policy Directive. This includes ensuring chemical manufacturers bear the burden of proof of safety of their products and be required to provide full information on the health hazards associated with their chemicals as well as ensuring research into chemicals and chemical processes designed to reduce or eliminate negative environmental impacts of chemicals.

However, NCSL cannot support any reform of TSCA that preempts state regulations in this area. Section 15 of the bill entitled "Preemption" is a broad state preemption provision that adversely impacts states' abilities to protect their citizens. First, Section 15 prohibits states from enacting stricter or stronger chemical safety regulations than those provided for in the bill. Section 15 also greatly hinders states' abilities to protect their citizens by prohibiting states from continued testing and development of standards for chemical substances. This approach appears to contradict public safety and is an inappropriate exercise of federal authority in an area where states have acted appropriately.

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In the absence of federal action to address issues related to TSCA implementation, many state legislatures have enacted legislation to regulate individual chemicals. States have also begun to develop comprehensive state chemical policies that aim to establish broad and permanent frameworks to systematically prioritize chemicals of concern, close data gaps on those chemicals and restrict their uses in those states. We would encourage the federal government to engage in meaningful consultation with state legislatures before attempting to preempt such laws.

For nearly all federal environmental statutes, there are provisions to extend the reach of the federal government by delegation of program authority and/or provision of federal grants to support state implementation of environmental requirements in lieu of or in addition to the federal requirements. Any reform of TSCA should both preserve state rights to manage chemicals and provide resources for state level implementation, as NCSL supports the preservation of state authority to enforce chemical security standards that are more stringent than those established by the federal government. As such, NCSL has serious concerns with S. 1009 as it is currently structured.

NCSL welcomes the opportunity to work with the Committee as it moves forward on this legislation to ensure that state authority is maintained. Please contact NCSL staff, Melanie Condon (Melanie.condon@ncsl.org) on environmental issues and Susan Parnas Frederick (susan.frederick@ncsl.org) on issues related to preemption of state authority.

Sincerely,

Representative John McCoy, Washington
Co-Chair, NCSL Natural Resources and Infrastructure Committee

Senator Ross Tolleson, Georgia
Co-Chair, NCSL Natural Resources and Infrastructure Committee

Representative Jim Gooch Jr., Kentucky
Co-Chair, NCSL Natural Resources and Infrastructure Committee

Senator John C. Watkins, Virginia
Co-Chair, NCSL Natural Resources and Infrastructure Committee

Assemblymember William C. Horne, Nevada, Co-Chair NCSL Law and Criminal Justice Committee

Representative Eric Watson, Tennessee, Co-Chair NCSL Law and Criminal Justice Committee

Attached: NCSL Federal Chemical Policy Reform Policy Directive

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Federal Chemical Policy Reform Policy Directive

NCSL Natural Resources and Infrastructure Standing Committee

The Toxic Substances Control Act (TSCA) of 1976 provides the US EPA with authority to require reporting, record-keeping and safety testing of chemical substances and/or mixtures. TSCA also gives EPA the power to restrict the use of chemicals. Certain substances are generally excluded from TSCA, including food, drugs, cosmetics and pesticides.

Since its enactment, increasing evidence linking toxic chemicals to adverse human health effects has eroded the public's confidence in the safety of consumer products containing toxic chemicals, prompting many state legislatures to act. In the absence of Federal action, states have passed legislation to regulate individual chemicals. States have also begun to develop comprehensive state chemical policies that aim to establish broad and permanent frameworks to systematically prioritize chemicals of concern, close data gaps on those chemicals and restrict their uses in those states. Appropriate modifications to federal law will help enhance public confidence and the efforts of the state governments.

Current federal chemical policy has not kept up with modern science. The science of testing chemicals and understanding their health or environmental effects has improved considerably since TSCA was enacted. NCSL believes TSCA should be updated to reflect the advances in science and technology to better evaluate and regulate chemicals.

TSCA's failures have caused the United States to fall behind our trading partners in the quality of our public health and environmental standards, and these failures now threaten the competitiveness of our manufactured products in a world market that increasingly demands safer chemicals and products.

Modernizing TSCA can help assure that we protect the nation's interest in a strong American business of chemistry – and assure that the United States produces products that save lives, protect our children, make our economy more energy efficient, and reduce greenhouse gas emissions.

Toxic Substances Control Act (TSCA) Reform

NCSL encourages Congress to reform and modernize The Toxic Substances Control Act (TSCA) of 1976. At a minimum, NCSL believes proposed TSCA reform legislation should embody these policy elements:

Act on the Harmful Chemicals First and Promote Safer Alternatives

Persistent, bioaccumulative and toxic chemicals (PBTs) are uniquely dangerous and should be phased out of commerce except for critical uses that lack viable alternatives. Exposure to other toxic chemicals, like formaldehyde, that have already been extensively studied should be reduced to the maximum extent feasible. Research into chemicals and chemical processes designed to reduce or eliminate negative environmental impacts of chemicals should be expanded, and safer chemicals favored over those with known health hazards.

Ensure Broad Access to Mandatory Safety Data on All Chemicals

Chemical manufacturers should bear the burden of proof of safety of their products, and should be required to provide full information on the health hazards associated with their chemicals, how they are used, and the ways that the public or workers could be exposed. The public, workers, and businesses should have full access to such information.

Protect All People, and Vulnerable Groups, Using the Best Science

All chemicals should be assessed against a health standard that protects all people and the environment, especially the most vulnerable subpopulations, including children, low-income

people, racial and ethnic minorities, workers, and pregnant women. EPA should adopt the recommendations of the National Academy of Sciences for reforming risk assessment. Biomonitoring by the Centers for Disease Control and Prevention should be significantly expanded and used by EPA to assess the effects of pollution on people.

States Rights

State governments play a critical role in environmental regulation. For nearly all federal environmental statutes, there are provisions to extend the reach of the federal government by delegation of program authority and/or provision of federal grants to support state implementation of environmental requirements in lieu of or in addition to the federal requirements. Any reform of TSCA should preserve state rights to manage chemicals, and resources should be provided for state level implementation.

Toxics Release Inventory Reform

NCSL urges the EPA to continue to provide appropriate contextual materials to affected communities to accompany Toxics Release Inventory (TRI) reports to assure particularly that emergency response agencies will understand and be able to respond safely to chemical releases to protect the people who live in the vicinity of facilities required to file TRI reports.

The EPA and the reporting industries should continue working to ensure that the reported TRI data are communicated to the public in an understandable manner that includes a description of the risk of release specific chemicals posed to the public and emergency response teams, how these materials are managed to control release, and an assessment of the risk to public health and welfare in the event of regulated or accidental releases.

November 12, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
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The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
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Dear Chairman Upton and Ranking Member Waxman:

We the undersigned scientists and researchers thank you for your interest in reforming the Toxic Substances Control Act to achieve its original purposes. We are pleased to submit this letter for the record for the Environment and the Economy Subcommittee's hearing, "S. 1009, The Chemical Safety Improvement Act." The Toxic Substances Control Act, passed in 1976 with bipartisan support, was intended to create a system to protect the public from the effects of harmful chemicals. It is widely acknowledged to have failed and to require an overhaul. We are concerned that the current bill to reform TSCA (S. 1009) does not adequately address the most important deficiencies in U.S. chemical regulation.

Since World War II, chemical production and use in the U.S. has increased dramatically. There are currently more than 80,000 chemical substances registered for use in U.S. commerce; several thousand of them are manufactured or imported in excess of 1 million pounds each every year.

We have good reasons to be concerned about widespread human exposure to chemicals in use. Scientists have developed the ability to detect trace chemicals in the human body and have shown that many Americans are exposed daily to dozens of chemicals linked to potentially harmful health effects. The federal Centers for Disease Control and Prevention sponsors the National Health and Nutrition Examination Survey.[1] It is a nationwide representative study of the population that measures chemicals in blood and urine and consistently finds hundreds of chemicals in Americans, particularly in pregnant women and children.[2]

Dozens of pollutants are now known to cross the human placenta from mother to child during pregnancy, some at concentrations known to adversely affect neurological and reproductive systems. It is also clear that subtle damages to individual children can result in major consequences at the population level. One study has estimated that three common pollutants

[1] Centers for Disease Control. 2013. Report on Human Exposure to Environmental Chemicals. National Health and Nutrition Examination Survey, http://www.cdc.gov/exposurereport/.
[2] Woodruff TJ. 2011. Environmental Chemicals in Pregnant Women in the United States: NHANES 2003-04. Environmental Health Perspectives. 119(6): 878-85

alone – mercury, lead and organophosphate pesticides – result in a total decrease of 40 million IQ points among American children ages 0 to 5 years as a group.[3] Laboratory and observational studies suggest that scores of other widely used chemicals may also cause toxic effects, but in many cases the extent of the risks to children has not been adequately determined.

Many of the chemicals detected in people's bodies are released from industrial sites into air and water and ultimately reach the food supply. Thousands more are intentionally added to consumer products. While regulatory programs for air and water have made improvements, TSCA has failed to protect Americans from chemicals. Modeling suggests that chemicals used in household consumer products can pose a more direct exposure risk for the general population than chemicals with only industrial uses.[4]

Many chemicals have not been adequately studied for their effects on human health, primarily because TSCA does not require manufacturers to ensure the safety of the chemicals they produce. The U.S. Environmental Protection Agency (EPA) has insufficient authority to require health and safety data, and insufficient resources to conduct the testing itself.

EPA leadership recently declared that "absent statutory changes, the Agency will not be able to successfully meet the goal of ensuring chemical safety now or in the future."[5] As scientists and public health researchers, we urge you to create a modern and robust system that will allow EPA to fully assess chemical hazards and protect public health. A reformed TSCA should also be harmonized with chemical regulations in Europe, Japan, Canada, and Australia; the U.S. does not need to reinvent the wheel.

Specifically, we urge you to address the following principles in any effort to update the Toxic Substances Control Act:

- **Chemicals cannot be considered "innocent until proven guilty"**

Currently under TSCA EPA lacks health and safety data for many widely used chemicals, which poses a catch-22 because the agency must have information to suggest a chemical poses health risk or probability of widespread exposure in order to compel manufacturers to test their chemicals for safety. In this way the system considers chemicals to be "innocent until proven guilty".[6] This flawed approach has meant that highly toxic chemicals are legally produced in large quantities unless data can be generated to demonstrate that they pose health risks. Manufacturers must take responsibility for ensuring the safety of the chemicals they produce, and should be required to produce health and safety data. Furthermore EPA must have the authority to mandate health and safety data for new chemicals, or a trigger for additional data to

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[3] Bellinger DC. 2011. A Strategy for Comparing the Contributions of Environmental Chemicals and Other Risk Factors to Neurodevelopment of Children. Environmental Health Perspectives 120(4):501-07.
[4] Wambaugh JF, et al. 2013. High-Throughput Models for Exposure-Based Chemical Prioritization in the ExpoCast Project. Environmental Science and Technology. 47:8479-88.
[5] GAO. 2013. Toxic Substances: EPA has increased efforts to assess and control chemicals but could strengthen its approach. U.S. Government Accountability Office. GAO-13-249.
[6] Lohmann R, et al. 2013. Science Should Guide TSCA Reform. Environmental Science and Technology. 47(16):8995-6.

be produced and a second safety review completed once the chemical reaches widespread production.

- **Congress must authorize EPA to restrict chemicals that threaten human health**

EPA is currently only authorized to address the "unreasonable risks" that chemicals pose to human health or the environment. When a chemical fails even this weak safety standard, the agency faces unreasonably burdensome requirements when it attempts to restrict the chemical's use. Efforts to improve TSCA must provide a greater degree of public health protection, as is legally mandated in the laws governing food packaging, where a chemical must be "safe for the intended use". Furthermore, EPA must be directed to explicitly evaluate and protect the groups most vulnerable to chemical contaminants. Many pollutants are most harmful to the developing fetus, young children or people suffering from chronic diseases. Exposures to chemicals are not evenly distributed across the population, but differ based on employment, community of residence, race and socioeconomic status.[7] As a result, certain sub-groups of Americans bear a disproportionate burden of chemical exposure.[8,9] The proposed TSCA reform bill (S. 1009) will not equip EPA with the information nor the authorities to fully control hazardous chemicals, nor ensure protection is equitable.

- **Secrecy claims should be accepted only if substantiated and not be permanent**

EPA's Inspector General has found that EPA's practices of shielding confidential business information are "predisposed to protect industry information rather than to provide public access to health and safety studies."[10] Recent reviews by the agency have revealed that companies overuse provisions designed to protect trade secrets.[11] EPA should have the power to require periodic re-substantiation of secrecy claims, with the goal of providing the maximum amount of information to scientists and researchers who study chemical behavior, toxicity and human exposure. All secrecy provisions should sunset after a few years. After this time, information should be publicly available, including site-specific production data.

As part of the reform of chemicals policy, open data sharing should be considered an integral goal. Many businesses, particularly secondary users of chemicals and retailers, are seeking more sustainable products and using more sustainable practices. These steps are stymied when data about chemicals and other materials are not available. Open disclosure of health and safety data, or the lack of health and safety data, will support these efforts and help businesses, as well as consumers and labor, to take direct steps to reduce their own exposure to hazards and risks. The

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[7] Tyrrell J, et al. 2013. Associations between socioeconomic status and environmental toxicant concentrations in adults in the USA: NHANES 2001-2010. Environ Int. 23(59C):328-335.

[8] Morello-Frosch RM, et al. 2013. Understanding the Cumulative Impacts of Inequalities in Environmental Health: Implications for Policy. Health Affairs 32(8): 879-887.

[9] Landrigan PJ, et al. 2010. Environmental Justice and the Health of Children. Mount Sinai Journal of Medicine. 77(2):178-87.

[10] EPA OIG. 2010. EPA Needs a Coordinated Plan to Oversee Its Toxic Substances Control Act Responsibilities U.S. EPA Office of Inspector General http://www.epa.gov/oig/reports/2010/20100217-10-P-0066.pdf

[11] EPA. 2013. Declassifying Confidentiality Claims to Increase Access to Chemical Information. U.S. EPA http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html

reform effort should include provisions for data disclosure for all chemicals in ways that are usable by outside audiences. The approach should also include use and development of metrics that allow for comparison of different chemicals with regard to attributes of health and safety.

- **EPA must comply with modern scientific principles in its assessments of chemical risks.**

EPA risk assessments should be required to conform to the recommendations of the National Academy of Sciences (NAS).[12] The NAS has urged EPA to better assess the scientific weight of evidence on chemical toxicity, and characterize data gaps and uncertainty around its decisions. EPA must assess human variability in both exposure to chemicals and sensitivity to toxic effects. This should explicitly include the aggregate effects of chemical mixtures.[13] Furthermore NAS has called for a unified approach to considering cancer and non-cancer hazards. This would mean that EPA should assume that low levels of exposure to chemicals are associated with some level of risk unless sufficient data is available to contradict this assumption.[14] Previous bills to reform TSCA have called for EPA to comply with the recommendations of the NAS, but that language has been stripped from the current bill.

- **EPA must move quickly to screen new and existing chemicals**

EPA's previous efforts to evaluate the hazards posed by high production volume chemicals, potential endocrine disruptors, or, most recently, to assess risks of 83 high priority chemicals, have been subject to numerous delays. Without clear authority, statutory deadlines and funding, EPA scientists will be unable to efficiently review and assess the thousands of industrial chemicals produced in high volumes. For example, the U.S. Government Accountability Office (GAO) found that at the current pace it could take EPA at least 10 years to assess just 83 chemicals of high concern, not to mention hundreds of other widely used and poorly studied chemicals.[15] Any new legislation that charges EPA with conducting chemical safety evaluations must also equip the agency with financial and personnel resources to perform the task adequately and in a timely manner. It must also include clear deadlines for chemical prioritization and assessment.

- **Scientists are willing to help**

As scientists, researchers and public health professionals, we have dedicated our professional lives to better understanding chemicals' effects on human health and the environment. On the basis of this research we conclude that TSCA must be reformed to provide EPA with the authority it needs to fill data gaps and to restrict chemicals that pose clear risks to people and the environment. The scientific community has valuable expertise and must be at the table as TSCA

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[12] National Academy of Sciences. 2009. Science and Decisions: Advancing Risk Assessment. National Research Council of the National Academies.
[13] Lohmann R, et al. 2013. Science Should Guide TSCA Reform. Environmental Science and Technology. 47(16): 8995-6.
[14] Woodruff TJ, et al. 2011. The Need For Better Public Health Decisions On Chemicals Released Into Our Environment. Health Affairs. 30(5):957-967.
[15] GAO. 2013. Toxic Substances: EPA has increased efforts to assess and control chemicals but could strengthen its approach. U.S. Government Accountability Office. GAO-13-249.

is rewritten. With scientific input, we can learn from past mistakes and benefit from decades of research on chemicals' environmental fates and effects. Only then will we collectively be able to protect public health from these chemical hazards.

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June 12, 2013

The Honorable John Shimkus
Chairman
House Energy & Commerce Committee
Subcommittee on Environment & Economy
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Paul Tonko
Ranking Member
House Energy & Commerce Committee
Subcommittee on Environment & Economy
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Shimkus and Ranking Member Tonko:

The undersigned are thirty-four law professors, legal scholars, and public interest lawyers from across the country who have years of collective experience in the fields of administrative, public health, and environmental law, with a particular focus on state and federal toxics policy. In view of tomorrow's hearing, we write to express serious reservations with the "Chemical Safety Improvement Act," which was introduced by Sen. David Vitter and the late Sen. Frank Lautenberg on May 22, 2013, in an effort to reform the Toxic Substances Control Act. Supporters have heralded the bill as a "historic step" toward fixing our broken framework for regulating chemicals on the market. However, for reasons explained herein, we cannot support the bill as written, which must be strengthened to overhaul current law and ensure that chemicals are safe for people, particularly vulnerable populations such as children.

In our expert opinion, the bill:

- Essentially preserves the same inadequate safety standard used in current law, which has been read by at least one court to require the U.S. Environmental Protection Agency (EPA) to engage in an onerous balancing of costs and benefits to justify restrictions on toxic chemicals;

- Retains the same obstructive standard of judicial review that appears in current law, which requires judges to demand substantial evidence from EPA to justify any safety determination or restriction of a chemical that poses risks to public health and the environment;

- Contains sweeping preemption language that would prevent states from enforcing existing, and adopting new, laws designed to supplement federal law in protecting people and the environment from exposures to harmful substances; and

- Takes the extraordinary step of making any safety determination by EPA dispositive on the question of whether a chemical is safe in federal and state courts. This would effectively bar judges and juries from taking into account other relevant evidence regarding the safety of a chemical, particularly new evidence developed after the determination is made.

Here are our four major concerns presented in detail:

Safety Standard. The bill defines "safety standard" as one that "ensures that no *unreasonable risk* of harm to human health or the environment will result from exposure to a chemical

substance." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 3(16) (emphasis added). This definition fundamentally reproduces the same safety standard found in current law. *See* Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a). Unlike strictly health-based standards (*e.g.*, "reasonable certainty of no harm"), laws that use "unreasonable risk" language have been interpreted to require EPA to complete a complex balancing of costs and benefits before the agency can impose a restriction on a chemical to address safety concerns. *E.g.*, John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 Ecology L.Q. 721 (2008); *see also* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 Vand. L. Rev. 1817 (2009). Therefore, even without language in the safety standard directing EPA to restrict a chemical using the "least burdensome requirements," Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a), by retaining the "unreasonable risk" language, the Chemical Safety Improvement Act might be read to place a heavy burden on EPA to impose even modest restrictions on a chemical. As a result, we believe that the same outcome in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991) (striking down EPA asbestos ban and phaseout rule) could be possible under the safety standard proposed in this bill, particularly with the heightened judicial review discussed in the next paragraph.

Judicial Review. Courts typically use a reasoned decisionmaking standard to review agency actions, meaning they will not strike down a regulation unless an agency has acted in an arbitrary or capricious manner. *E.g.*, *Allied Local & Regional Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 77 (D.C. Cir. 2000) (EPA consideration of factors listed in statute "adequate to constitute reasoned decisionmaking"); *see also* Administrative Procedure Act, 5 U.S.C. § 706. In contrast, the Chemical Safety Improvement Act, like the Toxic Substances Control Act, would require courts to apply a heightened standard of judicial review when evaluating rules made pursuant to the bill. Specifically, courts would have to set aside rules requiring the development of more test data, safety determinations, and restrictions on chemicals unlikely to meet the safety standard if, in their opinion, EPA has not supported them with "substantial evidence." Chemical Safety Improvement Act, S. 1009, 113th Cong. § 16(2). In practice, this standard can be read to "impose[ ] a considerable burden" on EPA to develop a record that can withstand a hard look from courts, particularly when all of the other procedural hurdles in the bill are factored in. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991), quoting *Mobile Oil Co. v. Fed. Power Comm'n*, 483 F.2d 1238, 1258 (D.C. Cir. 1973).

Preemption. The Chemical Safety Improvement Act would appear to largely preempt state regulations designed to protect public health and the environment from exposure to harmful chemicals. It would preempt existing and future state regulations that: require the development of test data or information on chemicals for which companies have to submit similar information to EPA; restrict the manufacture, processing, distribution, or use of a chemical after EPA has issued a safety determination for that chemical; or require notification for the use of a chemical substance if EPA has determined that it is a significant new use that must be reported to the agency. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(a). The bill also would prohibit states from creating new restrictions on the manufacture, processing, distribution, or use of a chemical that EPA has classified as high- or low-priority. *Id.* § 15(b). This preemption provision is sweeping in nature and raises serious questions as to whether states could even enact or continue to enforce laws that simply require companies to disclose information about

chemicals to consumers or require that products carry warning labels. Numerous states have passed laws in recent years in the absence of federal regulatory action to protect the public from toxic chemicals. *E.g.*, Safer Chemicals Healthy Families, *Healthy States: Protecting Families from Toxic Chemicals While Congress Lags Behind* (2010), http://www.saferstates.com/attachments/HealthyStates.pdf. If this bill were to become law, it would perpetuate many of the Toxic Substances Control Act's shortcomings while preventing states from protecting public health and the environment in the absence of a robust federal law — or in the case of a strong federal regulatory framework, from complementing EPA's efforts to achieve this important goal.

Private Remedies. The bill takes the extraordinary step of making a safety determination by EPA admissible in any federal or state court and dispositive as to whether a chemical substance is safe. Chemical Safety Improvement Act, S. 1009, 113th Cong. § 15(e). As a result, the bill's section on private remedies could significantly encroach on the right of judges and juries to evaluate and weigh relevant evidence regarding the potential injuries caused by toxic chemicals. In turn, this could have the effect of granting chemical companies immunity from legal actions by private parties once EPA has issued a positive safety standard determination, even when subsequent evidence calls into question the agency's reasoning.

In view of these issues, and others identified by public health and environmental groups, we believe the Chemical Safety Improvement Act preserves some of the most problematic features of the Toxic Substances Control Act, while making it harder for state and private actors to ensure the safety of chemicals in the absence of a strong federal backstop for regulating these substances. As a result, the bill, as currently drafted, takes a step backward in the protection of public health. We respectfully ask that the bill be made stronger to achieve meaningful reform of current toxics law and are available to provide substantive recommendations as needed.

Thank you for the opportunity to offer comments on reforming federal regulation of toxic chemicals. We ask that you submit this letter for the record.

Sincerely,

Note: Institutions listed for identification purposes only. The signators do not purport to represent the views of their institutions.

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cc: The Honorable Fred Upton, Chairman, House Energy & Commerce Committee
The Honorable Henry Waxman, Ranking Member, House Energy & Commerce Committee

Principles for Meaningful TSCA Reform

Toxic Substances Control Act ("TSCA") reform is needed to keep families safe from harmful chemicals that are in everything from children's toys and drinking water to consumer products that cause harm to children and pregnant women; however, certain provisions in S. 1009, "The Chemical Safety Improvement Act," wipe out good state laws and take away the right to sue companies that poison us. A plain reading of the relevant sections make this clear, as do the bill's findings where it states: "*...for purposes of promoting uniform protections through regulation of chemical substances in commerce, to minimize undue burdens on commerce, and to minimize burdens on States, specified actions by the Administrator should preempt requirements by states and political subdivisions of states that relate to the effects of or exposure to a chemical substance...*". (See S.1009, pg. 4, lines 1-9.) Courts generally hold that the term "requirements" encompasses both state statutory law and state common law, which is law defined by state courts and juries. The preemption provisions of S.1009 are made that much worse by the bill's inadequate safety standard and provisions for judicial review.

AAJ cannot support the bill as currently drafted until several provisions critical to ensuring public health and safety are appropriately addressed. These provisions include:

Preemption

- The bill contains sweeping preemption language that would supplant common law remedies and prevent states from enforcing existing or adopting new laws designed to supplement federal law to protect people and the environment from exposures to harmful substances.
- There are practical limits to how effective federal regulation alone can be in protecting the public. Just because a chemical is deemed "safe" by a federal regulator should not mean that the manufacturer's duty to protect the public ends. If it turns out that a manufacturer learns additional information about the safety of its product, or the manufacturer hid information from the public and injuries occur as a result, individuals should have the right to hold that manufacturer accountable. In addition, state law is critical to shedding light on new information. The limits on federal resources, rapidly changing technologies and the ever-expanding proliferation and use of chemicals, can prevent sufficient testing or regulation at the federal level.

Private Remedies

- The bill takes the unprecedented step of making EPA safety determinations admissible *and determinative* in both state and federal courts on the question of whether a chemical is safe. This would override all state law regarding evidence and procedure and bar judges and juries from taking into account relevant evidence regarding the safety of a chemical, particularly new evidence or science developed after an EPA determination is made.
- Forcing state courts to make admissible a singular determination of safety is problematic in and of itself because science is always changing and technology updating, but this is especially true if the basis of that determination is flawed because it fails to consider all relevant scientific sources. As explained below, this compounds the negative impact of making an EPA safety determination the final word on a chemical's dangers. The private remedies provision of the bill essentially forces courts to perpetuate outdated or inaccurate

determinations made by the EPA, even when they have been solidly refuted by the scientific community, until the EPA takes additional action.

- Considering the above, it is imperative that this Act does not foreclose the right of any party in litigation to introduce countervailing evidence even where an EPA determination exists. The Act should make clear that the EPA's science determination is intended to be an evaluation to comply solely with TSCA and is not intended to define what is considered a reasonable basis for analyzing data for other purposes including determining what evidence may be considered by a jury.

The Safety Standard

- Although the prior 'least-burdensome' language from existing TSCA has been removed, the bill preserves the same inadequate safety standard used in current law, which has been interpreted by courts to require the EPA to engage in an onerous balancing of costs and benefits to justify restrictions on toxic chemicals. The bill defines 'safety standard' as one that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance—a standard that is not a strictly health-based determination and one which has been interpreted to require a cost-benefit analysis because the language implies there is such thing as reasonable or acceptable risk to human health or the environment. As a result, the EPA may not be able to ban a substance it feels is too harmful to public health and safety, just as it failed to ban asbestos under the current TSCA in *Corrosion Proof Fittings v. EPA*.
- If the intention is to implement a strictly health-based standard, then to eliminate uncertainty about what the standard is, new language should be used to make clear that the standard is one that is purely health based. Additionally, language in the "Intent of Congress" section confuses the issue further by stating that the EPA must balance the safety of American consumers against unduly impeding chemical manufacturing. (See pg. 6, lines 19-25; pg. 7, lines 1-5.)
- The bill's definition of 'best available science' may be construed to limit the science considered when making a safety determination. At a minimum, the EPA should be able to evaluate all relevant health and safety studies including inconclusive but suggestive studies when making a safety determination.

Judicial Review

- The bill places the burden on the EPA to prove a chemical is unsafe, rather than requiring a manufacturer seeking to market a chemical prove its chemical is, in fact, safe.
- The bill also retains the same obstructive standard of judicial review that appears in current law, which requires judges to demand substantial evidence from the EPA to justify any safety determination or restriction of a chemical that poses risks to public health and the environment. Specifically, courts would have to set aside EPA rules requiring the development of more test data, safety determinations, and restrictions on chemicals unlikely to meet the safety standard if, in their opinion, the EPA had not supported them with 'substantial evidence.' In practice, this standard would impose a considerable burden on the EPA to develop a record that can withstand a hard look from courts, particularly when all of the other procedural hurdles in the bill are factored in.

TSCA Reform Must Protect Families Hurt by Toxic Chemicals

If no one is accountable, no one is safe; TSCA reform must not preempt state law

The Toxic Substances Control Act ("TSCA") does not protect the public from dangerous chemical substances and should be updated; however, TSCA must be reformed in a way that explicitly preserves states' rights to protect their own citizens. States must be able to continue to enforce: 1) state statutory laws that are more protective of human health than the federal standards; and 2) state tort laws which give Americans the right to file a lawsuit if they are injured or killed by toxic chemicals. Certain proposals to reform TSCA, including S. 1009 as it is currently drafted, would preempt this ability of states by wiping out state statutory laws and citizens' rights under state tort law.

The ability of states to enact chemical safety laws is critical to the protection of public health, especially when it comes to shedding light on new information regarding the dangers of chemical substances. Chemical testing and regulation at the federal level is often limited by federal resources, rapidly changing technologies, and the ever-expanding proliferation and use of chemicals. In response, most states have enacted laws to protect the health of their citizens from dangerous chemical substances, reflecting the idea that states are often in the best position to know what laws are necessary based on the unique needs and health risks assessed at the state and local levels. This complementary role of the states must be preserved to guide our continued understanding of the dangers of chemical substances and aid a strong federal regulatory system.

Just as preserving states' rights to enforce state chemical laws is vital to protecting human health and safety, it is imperative that TSCA reform measures ensure injured Americans can pursue claims against chemical manufacturers when their dangerous products cause serious injury or death. Just because a chemical is deemed "safe" by a federal regulator should not mean that the manufacturer's duty to protect the public ends. If a manufacturer learns additional information about the safety of its product or the manufacturer hid information from the public or the EPA, Americans should have the right to hold that manufacturer accountable in state and federal court.

The following are examples of toxic chemical and exposure cases which would never have been filed if S. 1009 as it is currently written with its preemption provisions were the law. These cases highlight the importance of preserving state tort laws in order to protect consumers, families, and children from the health and environmental hazards of toxic chemical substances:

1) School drinking water causes cancer (chrome)[i]

22 students and 6 teachers at Suva Elementary & Intermediate School in California were diagnosed with various forms of cancer, including leukemia & bone cancer, over an 8-year period thanks to toxic pollutants emitted from a nearby chrome-plating facility. Numerous teachers reported miscarriages during the same time period and in 1998, 7 families and Communities for a Better Environment filed lawsuits. The chrome-plating facility agreed to settle these claims for an undisclosed amount, abandoned the chrome-plating operations of the facility, and donated $25,000 to an environmental awareness foundation.

2) **Love Canal - birth defects, cancer, and miscarriages (benzene, dioxin, toluene, benzoic acid, lindane, trichloroethylene, dibromoethane, benzaldehydes, methylene chloride, carbon tetrachloride, chloroform)**[ii]

Hooker Chemical (now Occidental Petroleum Corporation) dumped more than 20,000 tons of toxic waste in the unfinished Love Canal during the 1940s and 50s. In 1953, the canal was buried over and sold to the local school district for $1 with a caveat explaining the waste dumping. Over the next 20 years toxic chemicals burned through the storage drums and oozed into the ground of the working-class Love Canal section of Niagara Falls – seeping into basements, leeching into schools buildings, contaminating pipes, and polluting the air – and exposed more than 6000 citizens to over 240 industrial chemicals, particularly benzene and dioxin. Children suffered burns on their hands and faces from playing outside. Pregnant women exposed to these chemicals experienced heightened instances of reproductive problems including low birth weights, still births and a 300% increase in miscarriages. An astonishing 56% of children born in the area from 1974 to 1978 suffered birth defects such as extra teeth, eye defects, arterial defects, pernicious anemia, mental disabilities, kidney disease, epilepsy, auto-immune diseases and cancers including Leukemia. Thousands of families had to be evacuated and by 1998, nearly three thousand victim lawsuits were filed against the manufacturers. As a result, Love Canal was announced as the first ever federal health emergency for a non-natural disaster and paved the way for the well-known Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) – better known as Superfund. The cleanup of the damage took more than two decades and cost in excess of $400 million.

3) **Baby bottles cause birth defects (BPA (bisphenol A))**[iii]

The plastic strengthener BPA is an extremely common chemical that is most commonly used in food & drink storage containers, especially baby bottles, sippy cups, and baby formula cans. BPA exposure negatively effects the brain, behavior, and prostate, with research showing a connection between BPA and cancer, obesity, diabetes, heart disease, ADHD, and down syndrome. BPA's negative health effects are most pronounced in infants and young children and stunt fetal growth. This hormone-disrupting chemical blocks or mimics hormones and disrupts the body's normal functions, especially in pregnant women, fetuses, infants, and young children. BPA exposure in utero or before birth can cause genital deformities, impaired learning, increased aggression, early onset of sexual maturation, decreased levels of testicular testosterone, and decreased sperm production. In 2008, a class action lawsuit was filed against a manufacturer of baby bottle glass. The case resulted in a settlement for affected families and a 4-year injunction restricting the sale of BPA baby bottles. Since the onset of BPA-related litigation, 12 states have passed a BPA ban: California, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Minnesota, New York, Vermont, Washington, and Wisconsin.

4) **Semiconductor Clean Rooms cause Birth Defects (trichloroethane, freon)**[iv]

Semiconductor fabrication facilities are highly sensitive to contaminants so they are manufactured in clean rooms. The measures taken in clean rooms, including the use of toxic chemicals and industrial cleaners, are for the protection and benefit the actual semiconductor products, not the workers. In 1981, over 65,000 San Jose, CA residents were affected by drinking water contaminated by two local semiconductor factories when the factories' underground storage tanks leaked trichloroethane, Freon, and other industrial solvents into the local groundwater supply. The contamination caused higher rates of miscarriages and birth defects in

the neighborhoods affected by the leaks with children born to workers suffering from kidney disease, heart problems, cerebral palsy, autism, blindness, spina bifida, epilepsy, sterility, delayed language development, and brain malformations. Many of the children also suffered from physical or skeletal problems. The fact that the demand for semiconductor technology will not be receding any time soon only highlights the need for effective and comprehensive state and federal regulation complemented by the civil justice system to ensure the safety of workers and affected communities.

5) **Hexavalent chromium causes cancer (Erin Brockovich)**[v]
In the 1950s, a compressor station operated by utility company Pacific Gas & Electric began leaking chromium 6 into the surrounding groundwater in Hinkley, California. The chemical was used to prevent rust from corroding the company's water-cooling system. For more than two decades the residents were slowly poisoned as they drank, bathed and swam in the polluted water. Hinkley residents suffered numerous physical ailments, including intestinal problems, rotten teeth, tumors, and bloody noses. This known carcinogen also causes higher rates of lung cancer, respiratory system problems, allergies, burning eyes, ulcers, and skin sores. 650 victims filed suit in 1993 and were able to reach a settlement with PG&E including an injunction ending the use of hexavalent chromium and an agreement to clean up the affected area. The case prompted other utilities to take similar actions and inspired the film *Erin Brockovich.*

6) Children's toys cause developmental disorders (lead)[vi]
For years lead was used in a variety of household items including batteries, paint, glassware, and even children's toys. Lead, however, is a highly toxic metal that causes a wide range of health problems when absorbed into the human body, especially in young children. It affects the brain, blood, kidneys, and nervous system. It leads to anemia, learning disabilities, mental retardation, behavioral problems, hearing loss, seizures, and even death. Because of lead contamination, toy giant Mattell recalled over 1 million toys in 2007 in response to a class action lawsuit. The class action was filed on behalf of millions of children and families who received contaminated toys and settlement proceeds were used to pay for testing children for lead poisoning.

7) **Learning disabilities caused by candy (lead)**[vii]
A 2004 investigative series by the Orange County Register found ingredients, such as chilies and tamarind, were contaminated with lead from local factory emissions in Mexico. This resulted in high levels of lead in candies sold in the United States. The California AG, Center for Environmental Health, EHC, and other local officials sued more than 30 candy makers. A settlement was reached in 2006 in which three of the major candy makers, including Hersheys and Mars, agreed to strict standards for protecting children from lead exposure in candies imported from Mexico. The manufacturers are now required to use new manufacturing processes and packaging materials and conduct independent audits. This became the first time the industry entered into a binding agreement requiring them to ensure their products do not pose a health risk to children. The settlement was the driving force behind a California bill that banned lead tainted candies.

8) Libby, Montana (asbestos)[viii]
In 1999, the Seattle-Post Intelligence revealed that there had been hundreds of deaths and illness over a 70 year time period in Libby, Montana thanks to occupational and non-occupational

exposure to asbestos. North of Libby is a vermiculite mining facility owned formerly by Zonolite Corporation and later by W.R. Grace. Vermiculite contains a naturally occurring amphibole asbestos mix that is particularly toxic to humans. Residents were exposed to high levels of asbestos fibers & dust in the air and vermiculite materials that were used in local schools, parks, baseball fields, and public buildings. Not only does asbestos exposure cause Mesothelioma, but it causes higher rates of lung cancer, asbestosis, and pleural disorders. From 1979-1998, Libby residents suffered an asbestosis mortality rate 40-80 times higher than expected and a 20-40 percent increase in malignant and non-malignant respiratory deaths. Years later, after numerous individual and class-action lawsuits for asbestos-exposure, W.R. Grace Corporation was finally forced to expend nearly $250 million in clean-up costs, the largest clean-up settlement by a single corporation in Superfund EPA history. To date, at least $447 million has been spent on the cleanup, and the town remains under a public health emergency declaration.

9) Cancer and other diseases for military families - Poisoning America's Marines[ix]

It was recently unveiled that Marine Corps Base Camp Lejeune's main drinking water system has been contaminated with a variety of toxic chemicals as early as 1948 and exceeding safety levels since 1953. More than 1 million marine veterans and their family members have been exposed to chemicals and volatile organic compounds -- such as percholorethylene (PCE), trichloroethylene (TCE), BTEX, and vinyl chloride -- at rates sometimes 150 times higher than the recommended level. Most of them chemicals are found in legal solvents used in dry cleaning or to clean machinery and weapons. The Agency for Toxic Substances and Disease Registry found that drinking water contaminated with PCE and TCE can cause fatal disease such as lung cancer, breast cancer, rectal cancer, leukemia, and non-hodgkin's lymphoma. Exposure can also cause kidney cancer, prostate cancer, end-stage renal disease, auto-immune related skin disorders, Hodgkins disease, and neurological effects. PCE-contaminated drinking water causes lower birth weights for infants and more miscarriages. Children who exposed in utero to TCE and/or PCE have been found to have Leukemia, major heart defects, neural tube defects, cleft lip, eye defects, and deformed nasal passages. More than 1,000 babies were stillborn or died in infancy aboard the base from 1947 to 1987, according to a survey of death certificates filed at the local County Register of Deeds. Veterans began filing suit in federal court but most of these cases are still pending. Congress signed the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012 to expand healthcare benefits to marines and their dependants have suffered. While most of the service men and women will file suit under federal law, civilian residents and workers on the base will have to pursue litigation in state court.

10) Childhood leukemia - A Civil Action[x]

The Boston suburb of Woburn has been home for many years to leather-tanning factories and chemical factories producing arsenic-based products, textiles, and glue. In 1982 residents filed a class action against W.R. Grace and Beatrice Foods; this famous case centered on the alleged contamination of two municipal supply wells with toxic chemicals, primarily trichloroethylene and perchloroethylene. 12 children contracted the rare childhood cancer acute lymphocytic leukemia and 8 of these children lived with a ½ mile radius of each other. Adults suffered from high incidences of cancer, liver disease, skin rashes, vision problems, headaches, and miscarriages. A total of 16 children died because of their exposure to the toxic chemicals. After years of litigation, W.R. Grace settled with the plaintiffs and the case was later the basis for the movie A Civil Action.

[i] Perales et al. v. Chrome Crankshaft Co., et al., No. VC027180 and Communities for a Better Environment v. Chrome Crankshaft, Inc., No. VC028531 (Cal. Super. Ct., Los Angeles County, first Amended Complaint for Damages Filed Dec. 22, 1998, complaint for Civil Penalties filed Jan. 19, 1999); Olivio, Antonio, *Families' Lawsuit Targeting Factory's Contamination is Settled*, LA TIMES, Aug. 7, 2000, http://articles.latimes.com/2000/aug/07/local/me-181; *Fact Sheet: Lawsuits Save Children's Lives*, CENTER FOR JUSTICE DEMOCRACY, http://centerjd.org/content/fact-sheet-lawsuits-save-childrens-lives (last visited June 18, 2013); *Fact Sheet: Environmental Tort Lawsuits: Holding Polluters Accountable*, CENTER FOR JUSTICE DEMOCRACY (Jan. 23, 2007), http://centerjd.org/content/fact-sheet-environmental-tort-lawsuits-holding-polluters-accountable; Gold, Matea, *A School, Factories and Plenty of Fear*, LA TIMES, Feb. 27, 1999, http://articles.latimes.com/1999/feb/27/news/mn-12186; *Ca Suit Says Chrome Plating Facilities Tainted Schools' Water Supply* Perales v. Chrome Crankshaft Co., 16 NO. 18 ANDREWS TOXIC CHEM. LITIG. REP. 8 (1999)

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Preemption under TSCA

TSCA reform must preserve states' rights

As advocates for people harmed by toxic chemicals, AAJ strongly supports efforts to reform the Toxic Substances Control Act (TSCA), but in order for reform to effectively protect the American public, it is imperative that Americans' access to state courts is protected.

Some proponents of the recent TSCA reform bill, S.1009, the "Chemical Safety Improvement Act" (S.1009) will argue that TSCA reform must include *total* preemption. These supporters argue that total preemption promotes innovation and provides them certainty in manufacturing across states lines by establishing a uniform federal standard. What these proponents *won't* tell you is that *total* preemption eviscerates State laws—both statutory and common—thereby removing the ability to sue manufacturers when their products cause injury or death.

Just how bad is *total* preemption for Americans? Two legal experts in both tort law and environmental regulations, Professors Thomas O. McGarrity and Wendy E. Wagner from the University of Texas School of Law, recently commented on the total preemption language found in S.1009, opining:

> *"In our decades of research and writing on tort law and environmental regulation, we have never seen a pre-emption provision that intrudes more deeply into the civil litigation system at the state level than the one in this bill. If victims of toxic chemical exposure attempt to recover damages at the state level, their cases would have to be dismissed if the EPA had concluded — rightly or wrongly — that a chemical was safe."*

Proponents of *total* preemption may also argue that their position is bolstered by the fact that current TSCA actually contains preemption. Indeed, the current TSCA law does contain preemption language; however, that language is nowhere near as sweeping as current proposals such as S.1009. Moreover, the current law has not had the practical *effect* of preemption, nor was it intended by the 1976 Congress which enacted the law, as demonstrated by three principal reasons, namely:

1. The preemptive effect of the 1976 TSCA language has never been truly realized because the standard of review for regulating chemicals was so high that the EPA has only been able to ban five of the approximately 80,000 chemicals under its jurisdiction. With such limited federal regulation of chemicals under existing TSCA, the preemptive effect of the 1976 law just has not occurred. .

2. The U.S. Supreme Court's interpretation of how federal statutes preempt state statutory and common law has evolved significantly since 1976. The Court has found preemption of state laws not only when it is impossible to comply with both state and federal law as was the case in 1976, but now, the Court finds preemption when Congress has "occupied the field," or when compliance with a state law could "frustrate the purpose" of a federal law[i]. This has held true in circumstances even when, seemingly, Congress expressly and explicitly attempted to preserve state law.

3. This change in judicial interpretation of federal preemption did not go unnoticed. As the Court's interpretation of federal preemption changed, Congress recognized the need for greater precision in drafting anti-preemption language. Congress took great pains to insure that Title II

of TSCA - the Asbestos Hazard Emergency Response, which was passed in 1986 and amended in 1990, included very strong anti-preemption language.

Thus, while current TSCA may contain preemption language, it has not had the *effect* of preemption. It is paramount that any TSCA reform measure specifically protects the ability of states to regulate dangerous chemicals and allow their citizens to seek recourse when dangerous chemicals cause injury or death.

The ability of states to enact chemical safety laws is critical to the protection of public health, especially when it comes to shedding light on new information regarding the dangers of chemical substances. Chemical testing and regulation at the federal level is often limited by federal resources, rapidly changing technologies, and the ever-expanding proliferation and use of chemicals. In response, most states have enacted laws to protect the health of their citizens from dangerous chemical substances, reflecting the idea that states are often in the best position to know what laws are necessary based on the unique needs and health risks assessed at the state and local levels. This complementary role of the states must be preserved to guide our continued understanding of the dangers of chemical substances and aid a strong federal regulatory system.

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[i] *Wyeth v. Levine*, 555 U.S. 555 (2009).

November 12, 2013

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman:

We are writing as medical professionals to express our strong concern over the weaknesses of S. 1009, the "Chemical Safety Improvement Act" (CSIA) and are pleased to submit this letter for the record for the Environment and the Economy Subcommittee's hearing, "S. 1009, The Chemical Safety Improvement Act."

In a recently published paper in the prestigious journal *Cell*, Linda S. Birnbaum, director of the National Institute of Environmental Health Sciences and the National Toxicology Program, wrote that Americans' exposure to environmental chemicals is playing a growing role in causing disease. It is highly plausible that the widespread use of untested chemicals is contributing to alarming increases in the prevalence of a number of diseases, particularly those linked to disruption of the endocrine system. Health conditions related to hormone signaling such as diabetes and reduced sperm count have increased over the past decades. In addition, behavioral effects that may be related to prenatal chemical exposure, such as ADHD and autism, are also on the rise.

As Dr. Birnbaum wrote, "The proliferation of inadequately tested chemicals in commerce may be contributing to the skyrocketing rates of disease." The fact is that there is a great deal we do not know about the potential health effects of many chemicals currently marketed in the US.

Environmental chemicals that can disrupt the endocrine system pose a special risk to vulnerable populations such as infants, children, pregnant women and the developing fetus. Proper hormone signaling is critical during development, and we lack vital data on many chemicals' potential to disrupt these processes. As written, the CSIA fails to include strong protections for children as well as other vulnerable populations including workers, the elderly and those already compromised by disease. Legislation designed to repair the nation's broken chemical regulatory system must make it a priority to protect these vulnerable groups.

Meaningful chemical policy reform must also include a requirement for minimum data sets on new and existing chemicals, and here again the Chemical Safety Improvement Act, as drafted, falls woefully short. The first steps in patient care and treatment include collection of a health history and an assessment of symptoms. Physicians and other health care professionals require

this information to make an accurate diagnosis and to prescribe the best course of treatment. As experienced medical providers, we strongly believe the same principles should apply to the evaluation and regulation of chemicals produced and marketed in the United States. Adequate data collection is essential for accurate evaluation of a chemical's hazard or safety, followed by appropriate regulation as needed to prevent or remedy public health problems. Medical practitioners can't afford to make assumptions without facts, and neither should the government.

In the current regulatory framework established by the 1976 Toxic Substances Control Act, chemicals are presumed safe until proven otherwise. This paradigm allows a potentially toxic chemical to be marketed widely before enough data has been generated to demonstrate whether it is safe. This puts the public at risk, and here again the CSIA, as drafted, fails to address the problem. We need legislation that requires manufacturers to provide adequate data on the potential toxicity of a chemical before it is marketed, and that gives the Environmental Protection Agency clear authority to take regulatory action to protect public health as necessary. The EPA should also be required to make such decisions in a timely manner under clear deadlines.

We also have serious concerns about CSIA's proposed safety standard, which largely replicates the weak standard in TSCA. It merely requires that a chemical pose "no unreasonable risk of harm to human health or the environment" [Chemical Safety Improvement Act, S. 1009, 113th Cong. § 3(16)]. Implicitly, this means that "reasonable risks" are acceptable. Chemical safety standards should be based on "reasonable certainty of no harm."

Additionally, the CSIA's provisions governing confidential business information do not ensure that health professionals or the scientific community will have access to information needed to make informed decisions about public health and patient care. The bill makes it possible for companies to withhold the identity of the chemicals being evaluated in safety studies submitted to EPA. Even in emergency situations, CSIA allows disclosure of this information to treating physicians and nurses only when the specific chemical identity will assist in diagnosis or treatment. To fulfill its responsibilities, the medical community must have ready access to confidential information on chemicals that might harm or otherwise affect public health. Health professionals must have specific information on chemicals that the public encounters in daily life in order to determine whether particular exposures are relevant to their patients' health.

Finally, we are disturbed that the CSIA's broad language on state-level preemption could prevent states from implementing more stringent protections for their citizens. Although the Clean Air Act, the Clean Water Act, TSCA and many other federal environmental laws allow states to take more aggressive action than the federal government when necessary to protect their residents from potential environmental threats, such action would be severely limited under the Chemical Safety Improvement Act.

Reforming U.S. chemical regulatory policy is essential and overdue, but it should be done in a manner that adequately protects public health and vulnerable populations and that provides regulators and health care professionals with the data needed to make informed decisions. Medical practitioners strive to prevent and treat illness by evaluating their patients' health histories and symptoms and making informed assessments of the presence or risk of disease. The same precautionary and information-based assessment should be required in chemical policy reform.

Sincerely,

Debra Baseman, MD, FACOG
Princeton Medical Group

Aly Cohen, MD, FACR
Founder and Medical Director, Integrative Rheumatology Associates
Jones/Lovell Fellow, Arizona Center for Integrative Medicine

Barry H. Cohen, MD, FACP
Founder and Medical Director, Mercer Kidney Institute

Steven Cohen, DO
Nephrologist, Mercer Kidney Institute

Jennifer Lighter Fisher, MD
Pediatric Epidemiologist
NYU Langone Medical Center

Nicole Gordon, MD
Gastroenterologist, Atlanta gastroenterology Associates

Mark Hyman, MD
Founder and Medical Director, The UltraWellness Center
Chairman, Institute for Functional Medicine

Richard Joseph Jackson, MD, MPH, FAAP, Hon ASLA, Hon AIA
Professor and Department Chair, Director of the Center for Occupational & Environmental Health (COEH)
UCLA Fielding School of Public Health

Rebecca Jacobson, MD
Obstetrics and Gynecology

Jason S. James, MD
Chairman, Department of Obstetrics and Gynecology, Baptist Hospital of Miami
Medical Director, FemCare Ob-Gyn

Laura H. Kahn, MD, MPH, MPP, FACP
Research Scholar
Program on Science and Global Security
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Princeton University

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USC School of Medicine

Elizabeth Kieff, MD
Assistant Professor of Psychiatry and Behavioral Neuroscience
Director of Wellness Programs
The University of Chicago Pritzker School of Medicine

Eric J Kessler, MD
Private practice-Interventional Cardiology

Erwin Kuo, MD
Internal Medicine
Diplomat, American Board of Internal Medicine

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Clinician Scientist, Child & Family Research Institute
Professor, Simon Fraser University

Stephen B. Lewis, MD
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Executive Director, Arizona Center for Integrative Medicine
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Chairman, Department of Pediatrics
University Medical Center at Princeton

Robert Ostfeld, MD, MSc, FACC
Director, Cardiac Wellness Program
Associate Professor of Clinical Medicine
Montefiore Medical Center

Randi Protter, MD
Medical Director
Capital Health Center for Women's Health

Beverly Radice, MD
Medical Director
Princeton Regional Schools

John Routt Reigart II, MD
General Pediatrics, MUSC Children's Hospital

Rich Stagliano, MD
Founder and Medical Director, Live Fit Medicine

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

February 28, 2014

The Honorable Jim Jones
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Assistant Administrator Jones:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Friday, March 14, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 3 0 2014

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable John Shimkus
Chairman
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Shimkus:

Thank you for the opportunity to respond to the questions for the record following the November 13, 2013, hearing on "S. 1009, The Chemical Safety Improvement Act." Enclosed are the EPA's responses to the questions.

If you have any further questions, please contact me or your staff may contact Sven-Erik Kaiser in my office at kaiser.sven-erik@epa.gov or (202) 566-2753.

Sincerely,

[redacted]

Laura Vaught
Associate Administrator

Enclosure

House Committee on Energy and Commerce
Subcommittee on Environment and Economy
Hearing on "S.1009, The Chemical Safety Improvement Act"
November 13, 2013
Questions for the Record

The Honorable Henry A. Waxman

Transparency has been a significant problem under TSCA. Consumers, public health advocates, researchers, and state governments are often in the dark about chemical risks, even when EPA has data. This is because the statute prohibits EPA from sharing information that has been marked as Confidential Business Information, or CBI, but requires no substantiation of CBI claims. Current law includes no penalty for over claiming CBI.

The result is a system where the public has no access to any information about approximately 20% of the 83,000 chemicals on the TSCA inventory, and the chemical identities of 66% of new chemicals covered by pre-manufacture notices (PMNs) are marked CBI. EPA has been working to check these CBI claims, and has made significant strides to make more chemical information public, but the process requires significant public resources.

Waxman 1. Should TSCA reform legislation require upfront substantiation of CBI claims, and why is this important?

S. 1009 would require up front substantiation for some, but not all, CBI claims. The bill contains a long list of types of information that will be presumed to be CBI, without substantiation.

Response: The Administration's principles for reform of chemicals management legislation state that TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI) and that manufacturers should be required to substantiate their claims of confidentiality. This principle is important to assure transparency and public access to information.

Waxman 2. Does exempting large categories of information from the substantiation requirement comport with EPA's principles for TSCA reform?

Response: As indicated above, the Administration's principles for reform of chemicals management legislation include the need for stronger provisions for transparency and public access to information, including a requirement for the substantiation of confidentiality claims. Stronger provisions on transparency and increased access will ensure that legitimate CBI claims are protected while providing the American public with greater access to chemical information.

The relevant principle states: "TSCA reform should include stricter requirements for a manufacturer's claim of Confidential Business Information (CBI). Manufacturers should be required to substantiate their claims of confidentiality. Data relevant to health and safety should not be claimed or otherwise treated as CBI. EPA should be able to negotiate with other governments (local, state, and foreign) on

appropriate sharing of CBI with the necessary protections, when necessary to protect public health and safety."

One impact of EPA's review of CBI claims has been a significant decrease in the number of claims being made. For example, under the last Inventory Update Rule, manufacturers claimed that the use of a chemical in children's products was confidential 24% of the time. In the most recent version – the Chemical Data Reporting Rule, the rate of confidentiality claims for the use of a chemical in children's products dropped to 0.4%.

Waxman 3. Why does the EPA collect and publish information about what chemicals are used in children's products?

Waxman 4. Are there other types of uses that might be particularly relevant and important for the public at large and vulnerable populations?

Response to Questions 3 and 4: Chemical Data Reporting (CDR) information is used by the EPA to support risk screening, assessment, priority setting and management activities. Processing and use information reported in 2012 will help the EPA screen and prioritize chemicals for the purpose of identifying potential human health and environmental effects. Collecting the information every four years will assure that the public has timely access to current and improved data. This information will also provide the public with greater access to a wide range of information on those chemicals that are produced in large quantities. Improved data will enhance the agency's ability to more effectively identify and address potential chemical risks.

The 2012 CDR collected information on more than 7,600 chemicals in commerce including information on more than 350 chemicals used in children's products such as toys, playground and sporting equipment, arts and crafts materials, and furniture. In addition, manufacturers reported on more than 1,700 chemicals used in consumer products generally. Users of the CDR data are able to view chemicals with commercial and consumer uses and by geographic area for facilities where chemicals are being manufactured. This information helps inform potential exposures and would be relevant for the public and vulnerable populations.

For additional information on the 2012 CDR, see the Federal Register Notice for 2012 CDR reporting at: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0187-0393.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

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Minority (202) 225-3641

February 28, 2014

Mr. Cal Dooley
President and CEO
American Chemistry Council
700 2nd Street, N.E.
Washington, D.C. 20002

Dear Mr. Dooley:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Friday, March 14, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

American® Chemistry Council

March 14, 2014

Mr. Nick Abraham
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Re: Questions for the Record to Mr. Cal Dooley Dated February 28, 2014

Dear Mr. Abraham:

Attached are the responses of Mr. Cal Dooley to the additional questions for the record following the Subcommittee on Environment and the Economy's hearing on November 13, 2013 on S. 1009, the Chemical Safety Improvement Act.

Please let me know if you have any questions.

Sincerely,

[redacted]

Michael P. Walls
Vice President
Regulatory and Technical Affairs

Attachment: Cal Dooley QFRS 20131111 draft 20140314

Mr. Cal Dooley
American Chemistry Council
Responses to Questions for the Record Dated February 28, 2014

The Honorable Henry A. Waxman

General Response: ACC stands by our 2009 Principles for TSCA Reform. We firmly reject any insinuation that ACC has departed from our 2009 Principles in advocating for an efficient, effective and robust national chemical regulatory program.

ACC's 2009 Principles were developed as a general guide to the issues and areas that were anticipated to be addressed in TSCA reform. These principles could not be reasonably expected to address every detail in a statute as complex as TSCA. We note that several other organizations – notably the Environmental Protection Agency – developed principles that mirror many of the same issues addressed in ACC's. The other organizations' statements of principle, like ACC's, lack much of the detail which some Members insist on reading into ACC's Principles.

Q1. Does ACC still support providing EPA with sufficient resources to implement the requirements of TSCA?

Response: The relevant element of ACC's 2009 Principles for TSCA Reform states, in its entirety:

> EPA should have the staff, resources, and regulatory tools it needs to ensure the safety of chemicals.
> - EPA's budget for TSCA activities should be commensurate with its chemical management responsibilities.

The ACC principle as stated is clearly focused on a general need for EPA to have sufficient resources to implement TSCA reform, and speaks only to EPA having sufficient budget resources for that purpose. ACC supports EPA's having sufficient resources to implement the requirements of TSCA as it might be reformed.

Q2. Are ACC members willing to provide a portion of those resources through fees?

Response: ACC's 2009 Principles for TSCA Reform do not address the specific question of fees. Section 26(b) (15 U.S.C. § 2625(b)) of TSCA as it exists today provides that the Administrator may require the payment of a fee to defray the cost of administering certain elements of the program. Neither S. 1009 nor Mr. Shimkus' discussion draft (published February 28, 2014, well after the November 13, 2013 hearing that is the subject of this question) amend the fee provisions in section 26. ACC's expectation is that EPA would continue to have authority to establish and collect fees to support implementation of TSCA.

Q3. ACC has expressed support for S. 1009, but the bill falls short of your principle on resources – do you think the bill should be amended to ensure that EPA has sufficient resources?

Response: This question appears to imply that ACC should or could support TSCA reform only if each and every element of our 2009 Principles for TSCA Reform is included in a TSCA amendment, without exception. It is true that S. 1009 does not address the question of EPA resources. In our view, both S. 1009 and Mr. Shimkus' discussion draft (published on February 28, 2014, well after the November 13, 2013 hearing which is the subject of this question)

properly focus on getting the structure and parameters of necessary TSCA reform detailed first. In ACC's view, the resources made available to EPA to implement the program should be scaled to the scope of the program, rather than the amount of resources dictating the scope of the program.

Q4. ACC's 2009 principle for TSCA reform called for requiring upfront substantiation, and periodic resubstantiation, of CBI claims, without an exception for existing CBI claims or certain types of information. Does ACC still support those requirements?

Response: The relevant element of ACC's 2009 Principles for TSCA Reform stated, in its entirety:

> Companies and EPA should work together to enhance public access to chemical health and safety information.
> - EPA should make chemical hazard, use, and exposure information available to the public in electronic databases.
> - Other governments should have access to confidential information submitted under TSCA, subject to appropriate and reliable protections.
> - Companies claiming confidentiality in information submittals should have to justify those claims on a periodic basis.
> - Reasonable protections for confidential as well as proprietary information should be provided.

We note that S. 1009, and Mr. Shimkus' discussion draft (published on February 28, 2014, well after the November 13, 2013, hearing which is the subject of this question) both provide that the submitter of a claim for protection against disclosure should justify the claim and indicate a period for which protection is necessary. Under both S. 1009 and the House discussion draft, EPA has the authority to approve and modify the claim. Under both S. 1009 and the House discussion draft, the submitter has an opportunity to extend the period for which protection against disclosure is required. ACC believes this is a reasonable approach for up front substantiation and periodic resubstantiation consistent with our stated Principle.

Q5. Does ACC continue to support its principle that cost should not be a part of a safety determination?

Response: Yes. Both S. 1009, and Mr. Shimkus' discussion draft (published on February 28, 2014, well after the November 13, 2013, hearing which is the subject of this question) clearly separate cost and benefit considerations from the application of the safety standard in EPA safety determinations.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

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February 28, 2014

Dr. Richard A. Denison
Senior Scientist
Environmental Defense Fund
1875 Connecticut Avenue, N.W.
Suite 600
Washington, D.C. 20009

Dear Dr. Denison:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Friday, March 14, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

EDF
ENVIRONMENTAL DEFENSE FUND
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March 14, 2014

The Honorable John Shimkus
Chairman
Subcommittee on Environment and the Economy
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Shimkus:

Attached please find my responses to the written questions for the record I received in follow-up to the November 13, 2013 hearing held by the Subcommittee titled "S. 1009, The Chemical Safety Improvement Act."

I received one set of questions, from Committee Ranking Member Henry A. Waxman. Responses to each question are attached.

I greatly appreciate the opportunity to have testified before the Subcommittee on this very important subject, reform of the Toxic Substances Control Act.

Best regards,

[redacted]

Richard A. Denison, Ph.D.
Senior Scientist

cc: The Honorable Paul Tonko, Ranking Member

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Responses of Dr. Richard A. Denison
Senior Scientist, Environmental Defense Fund
to
Follow-Up Questions from Congressman Henry Waxman
Committee on Energy and Commerce
Subcommittee on Environment and the Economy
for the
Hearing on "S. 1009, The Chemical Safety Improvement Act"
held on November 13, 2013

The Honorable Henry A. Waxman

S. 1009 would not require new chemical applications to be accompanied by data and would not require testing of all existing chemicals. Instead, testing would continue to be required on a chemical specific basis under section 4. In fact, the bill explicitly authorizes EPA to allow new chemicals into commerce after determining that testing is needed and before receiving the results of that testing.

1. Should a reformed TSCA ensure that EPA gets more information about new chemicals at the pre-manufacture notice (PMN) stage?

RESPONSE: A reformed TSCA should ensure that a new chemical (or a significant new use of chemical) can only commence manufacture upon a determination by EPA that the chemical (or significant new use) is likely to meet the safety standard. Where insufficient information is available for EPA to make that determination, two options should apply:

a. Manufacture of the chemical (or of the chemical for the significant new use) cannot commence until the information is provided and EPA's makes the requisite determination.

OR

b. EPA imposes conditions on the chemical (or significant new use) sufficient for EPA to determine, despite the insufficiency of the information available, that the chemical or use is likely to meet the safety standard. An example would be where a company proposes three uses of a chemical and EPA has enough information to find two of the three are likely safe, but not the third. EPA could allow the chemical on the market for the first two uses, but prohibit the third use until sufficient data are received and analyzed to make the determination on the third use. Another example would be where EPA places limits on the chemical, such as a maximum production volume, use restriction, or release limit, that are binding on the company, based on which EPA could make the requisite determination.

In any case where EPA imposes conditions on a new chemical or significant new use (typically done through a consent agreement or order) – whether or not in response to a lack of information – it is essential that those conditions apply to any manufacturer or processor of the chemical. The most straightforward way to ensure this is to mandate that EPA issue a significant new use rule (SNUR) in

conjunction with the consent agreement or order that delineates those conditions and requires notification to EPA by any company proposing to make or use the chemical in a manner that does not comport with the conditions.

S. 1009 would change the determination that EPA must make before requiring testing under section 4, replacing the risk determination with a determination that the new data is needed to perform a safety assessment, to make a safety determination, or to meet information needs under other statutes. The bill does not provide authority to require testing for the review of the chemicals or in order to inform prioritization screening.

2. Should a reformed TSCA provide EPA with authority to require testing of new chemicals?

RESPONSE: My response to question 1 is germane to this question as well. I believe ideally there should be a requirement that new chemical notifications be accompanied by a robust safety information set. But it is most essential that there be: a) a requirement for EPA to make an affirmative safety decision prior to manufacture, and b) EPA authority and a mandate to either: i) withhold such a decision in the absence of sufficient information, or ii) impose conditions necessary for EPA to make an affirmative safety decision even in the absence of the information. If a new chemical with insufficient information is not allowed to commence manufacture except under conditions sufficient for EPA to make the "likely meets the safety standard" determination, companies have an incentive to provide needed information and there is an assurance that information gaps do not jeopardize public and environmental health.

Current TSCA does not restrict EPA's authority to require testing of new chemicals, so in this respect S. 1009 scales back EPA authority. Current TSCA does not, however, have a requirement for an affirmative safety determination to be made for new chemicals.

3. Should a reformed TSCA, if it requires a prioritization screening, provide testing authority to inform that screen?

RESPONSE: The retraction of TSCA's current authority for EPA to require testing for prioritization is a serious flaw in CSIA as introduced and that authority should be restored. (Again, it is important to note, however, that CSIA does address two other key flaws in TSCA's testing authority: it provides for EPA to require testing by issuing an order rather than by rulemaking; and it eliminates the requirement that EPA first show evidence of potential risk, or high production and high release or exposure, in order to require testing.)

The problems arising from the lack of authority under CSIA to require testing to inform prioritization decisions are compounded by other provisions of CSIA as introduced. First, there is no requirement that low-priority designations be based on sufficient information on both hazard and exposure to ensure confidence in an EPA determination that such a chemical is in fact likely to meet the safety standard. Second, under CSIA as introduced, such low-priority designations pre-empt state and local government authority to impose new requirements on such chemicals, and those designations are not judicially reviewable. Third, while lack of sufficient information can be "a factor" in making high-priority designations, such lack of information should be a sufficient basis by itself to designate a chemical high-priority. Fourth, there are no deadlines or data- or action-forcing steps in the provision authorizing EPA

to defer a prioritization decision due to lack of information. Other than a requirement that EPA solicit voluntary submissions of information on such chemicals, nothing precludes such chemicals from entering what could amount to an indefinite limbo. Finally, there is no requirement that EPA publicly identify chemicals for which it has deferred a prioritization decision and the basis for that decision.

Together, these provisions of CSIA as introduced would yield a situation where lack of data would lead to no decision or potentially an erroneous prioritization decision, with little or no transparency or incentive to address data gaps. Because many chemicals in commerce have significant gaps in available information on their hazard, use and/or exposure, lack of authority to ensure adequate information is developed could stymie the entire purpose of the prioritization process.

S. 1009 fails to require protection of vulnerable populations in safety determinations for chemicals and in risk management decisions. This fundamental flaw could put women, children, the elderly, the disabled, workers, and residents of hot spot communities at grave risk.

4. Do you think that a chemical that poses a serious or substantial risk to a vulnerable population should be able to pass a safety standard under a reformed TSCA?

RESPONSE: A safety standard under a reformed TSCA should be a health-based standard, and the standard should assure protection of vulnerable populations, including those subject to higher exposure, higher susceptibility, or both. Chemicals should be found to meet the safety standard only where risks to such populations have been assessed and found not to be significant.

5. Do you think that risk management decisions must ensure that significant or substantial risk to a vulnerable population should be addressed?

RESPONSE: Where a safety determination for a chemical finds that the chemical does not meet such a safety standard, it should be allowed to remain in commerce only where conditions or restrictions are imposed sufficient to ensure the standard is met – which includes protection of any relevant vulnerable populations.

One of the significant obstacles we have seen to implementation of TSCA, like other environmental laws, is the lack of resources afforded to EPA to carry out its essential public health mission. Yet S. 1009 creates significant new procedural requirements and hurdles to agency action without providing additional resources.

6. Should EPA have the resources necessary to effectively administer a reformed TSCA?

It is essential that EPA be afforded sufficient resources to develop and implement new policies and procedures and carry them out in an effective and efficient manner. The sheer magnitude of the problem – tens of thousands of chemicals in commerce the safety of which has never been assessed – poses major challenges and any system will likely take many years to work through this backlog. Nonetheless, while there is no magic number dictating the optimal pace and scope of progress in a new program, to be credible I believe the new program needs to operate on a scale that is significantly expanded over the status quo. All stakeholders should have a shared interest in having an ambitious program that makes decisions expeditiously and provides confidence to the market, consumer and the

general public that the program is working well and making serious and steady progress in tackling the problem. Assuring that outcome will require that sufficient, sustained resources are provided.

7. Should industry contribute a portion of those resources through user fees?

Industry should contribute a significant share of the resources needed to fund the full breadth of EPA activities under a reformed TSCA, which would include data collection and analysis and new and existing chemical evaluations, but also additional activities such as review of industry claims for protection of confidential business information. Some type of user fee is needed that could expand and modernize the fee provisions in current TSCA (Section 26), which apply only to new chemical reviews.

Similar fees are routinely applied to cover EPA substance reviews and related activities under laws regulating drugs and pesticides, where legislation has implemented specific fee systems, e.g., the Prescription Drug User Fee Act (PDUFA) and the Pesticide Registration Improvement Act (PRIA).

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225-2927
Minority (202) 225-3641

February 28, 2014

Mr. Andy Igrejas
National Campaign Director
Safer Chemicals, Healthy Families
1050 30th Street, N.W.
Washington, D.C. 20007

Dear Mr. Igrejas:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Friday, March 14, 2014. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

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February 28, 2014

Ms. Wendy Wagner
Joe A. Worsham Centennial Professor
The University of Texas School of Law
727 E. Dean Keeton Street
Austin, TX 78705

Dear Ms. Wagner:

Thank you for appearing before the Subcommittee on Environment and the Economy on Wednesday, November 13, 2013, to testify at the hearing entitled "S. 1009, The Chemical Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Sincerely,

John Shimkus
Chairman
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cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachment

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WENDY E. WAGNER

March 14, 2014

Nick Abraham
Legislative Clerk
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Shimkus,

Thank you for your request for more information regarding S.1009. My answers to the questions raised by the Honorable Henry A. Waxman are provided below. Please do not hesitate to let me know if you have any further questions.

1. **Given the requirements you have identified, do you expect EPA to take action to assess or regulate any chemicals in the near future? Can you estimate how long you think the delay could be before regulatory action would be taken under this bill?**

Under S.1009, EPA's regulation of chemicals could be even more sluggish than it is under TSCA. The bill narrows the aperture for the scientific evidence the agency may consider to justify regulation (see my written and oral testimony on the "Best Available Science" provision at the Nov. 13, 2013 hearing), while at the same time establishing new hurdles for the agency in demanding additional testing from manufacturers. See #6 below. The bill also imposes an entirely new set of procedural requirements on the agency as a prerequisite to regulation. See #5 below. These cumulative impediments add to the high burden already required of the agency to regulate chemicals under TSCA. If over the last thirty-five years, EPA has managed to regulate only five existing chemicals, then one might expect still less progress under S.1009, equating to perhaps to regulatory action on only about one existing chemical every ten years.

2. **Does the bill provide resources to EPA to meet the procedural requirements you identify?**

No. To my knowledge, there is no provision in the bill for added resources to enable EPA to implement the bill's many added requirements.

3. Would companies required to test chemicals under TSCA have a financial incentive to challenge a testing requirement?

Companies will have a financial incentive to challenge EPA's rules requiring more testing, even in cases where the companies do not expect to prevail in court. Litigation-backed comments appear to lead to the weakening of proposed rules, at least when the comments are submitted by regulated industry. *See, e.g.*, Wendy Wagner, Katherine Barnes, and Lisa Peters, *Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Emission Standards*, 63 ADMINISTRATIVE LAW REVIEW 99 (2011). Moreover, with respect to litigation, a simple, rational actor model predicts that a company will invest as much in litigating an EPA regulation as it expects to derive in profits as a result of the added delay of regulation. If litigation delays EPA's regulation by five years, for example, then a company may find it beneficial to challenge that rule if the cost of the litigation is less than the financial gains (e.g., interest from forgone testing, delay in regulatory restrictions) that it expects to recoup as a result of the delay. *See, e.g.*, Gordon C. Rausser et al., *Information Asymmetries, Uncertainties, and Cleanup Delays at Superfund Sites*, 35 J. ENVTL. ECON. & MGMT. 48, 49 (1998) (arguing that potentially responsible parties at Superfund sites may use their asymmetric information regarding their contributions to a site to delay EPA investigation and cleanup because delay brings great cost savings); Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729, 737-39 (making the case for how increased profits resulting from delay in regulation make it profitable in many cases for industry to judicially challenge regulatory requirements, regardless of the expected outcome on the merits).

Past experience also reveals that in many cases litigation against the agency is not brought by a single company but instead by trade associations on behalf of many members. To the extent this pooling of resources occurs for litigation, the company's individual financial benefits from litigation will be much lower to justify a rational investment in litigation. This financial calculation, moreover, brackets the possibility that the litigation might yield favorable precedent for the companies that could have positive spillover effects for other features of their businesses.

4. Is this type of scientific determination well suited to court review?

No -- judicial review of EPA's decisions to demand more testing or to regulate existing chemicals are not well suited to judicial review. The courts have struggled over the last three decades to identify the appropriate level of deference to afford agency scientific and technical choices, and their decisions have varied widely in the level of deference they afford to the agencies. *See, e.g.*, Howard A. Latin, *The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty*, 78 NW. U. L. REV. 583, 583 (1983) (arguing that courts lack adequate conceptual framework for dealing with factual uncertainties); Richard J. Pierce, Jr., *Two Problems in Administrative Law: Political Polarity on the District of*

Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 DUKE L.J. 300, 311 (arguing that courts often require "that agencies 'find' unfindable facts and support those findings with unattainable evidence"). In fact, one of the most criticized cases from within this larger set is the Fifth Circuit's review of EPA's effort to regulate asbestos under TSCA. *See, e.g.*, Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525, 548 (1997) ("In the six years that have passed since the Corrosion Proof Fittings opinion, the EPA has not initiated a single action under section 6 of TSCA...."). The courts' approach to the judicial review of science has also led to various perverse incentives for agencies to be even less transparent in their rulemakings. *See, e.g.*, Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUMBIA L. REV. 1613 (1995). Since the standard for judicial review under S. 1009 is the higher "substantial evidence" standard, moreover, EPA may face a less deferential judicial panel in the courts' review of its interpretation as compared to the "arbitrary and capricious" standard of the Administrative Procedure Act (APA).

5. **What other scientific determinations would the bill make judicially reviewable, and do you have concerns about the ability of courts to effectively review those decisions?**

S. 1009 imposes a number of science-intensive methodological and procedural requirements on EPA, including: 1) development of a "structured evaluative framework" before initiating its chemical oversight work; 2) publication of criteria for evaluating all data and information on which it relies to make any decision; 3) establishing a risk-based screening process for designating chemicals high or low priority for review; 4) development of a strategic plan to promote the development and implementation of alternative test methods and to promote non-animal tests; and 5) promulgation of procedural rules governing safety assessments EPA will conduct for each "high priority" chemical.

Some of these steps appear to be judicially reviewable – for example, the promulgation of procedural rules governing safety assessments – and other steps might be insulated from judicial review, particularly in cases when the agency does not promulgate a final rule. Yet the bill is ambiguous about which steps are judicially reviewable and which are not (see, e.g., S. 1009 § 6(b)(6)(B)). This ambiguity, in and of itself, is thus likely to lead to additional litigation over which regulatory products can ultimately be challenged in court. In addition and discussed in #4, the challenge that courts face in reviewing science-intensive rules is well-established in the literature.

6. Given the instruction to use the best available science, do you think it will be difficult for EPA to effectively demonstrate that additional data is needed?

Under S. 1009, EPA must establish the need for data as a condition for demanding more testing. Manufacturers could attempt to argue in opposing such a demand that EPA lacks a legal basis for requesting new data since the "best available evidence" is good enough for purposes of regulation. Hopefully such a circular and counterproductive reading of the bill will not prevail in court, but there is no guarantee in this regard.

It is also difficult to imagine how EPA will justify the need for new testing when it is not clear, absent that testing, what the new information will reveal. Regardless, the requisite showing of need threatens to impose an added evidentiary burden, and a potentially heavy one, on EPA before it can collect additional data from manufacturers. Already the Section 4 requirements of TSCA have led to a Catch 22 since EPA must establish that the chemical "may present an unreasonable risk of injury to health or the environment" as a prerequisite to requiring more testing, even for chemicals for which nothing is known. *See, e.g.,* Mary L. Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795, 1799 (1989). As a result of this burden, EPA has issued only 200 test rules over thirty years (there are roughly 80,000 existing chemicals in the inventory). By imposing possibly an even heavier evidentiary burden on the agency to acquire added testing under S. 1009, one could expect EPA to be still less successful in acquiring information upon which to base its regulatory decisions.

Respectfully,

[redacted]

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